### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 25, 2021

# MONTES ARCHIMEDES ACQUISITION CORP.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 001-39597 (Commission File Number) 85-1830874 (I.R.S. Employer Identification Number)

724 Oak Grove Ave., Suite 130 Menlo Park, CA (Address of principal executive offices)

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

94025 (Zip Code)

Registrant's telephone number, including area code: (650) 384-6558

 $\label{eq:Not-Applicable} \textbf{Not Applicable} \\ \textbf{(Former name or former address, if changed since last report)} \\$ 

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Soliciting material pursuant to Rule 14a-12 under the Exchange Ac  Pre-commencement communications pursuant to Rule 14d-2(b) und  Pre-commencement communications pursuant to Rule 13e-4(c) und	rt (17 CFR 240.14a-12) der the Exchange Act (17 CFR 240.14d-2(b))	
Securities registered pursuant to Section 12(b) of the Act:		
Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Units, each consisting of one share of Class A common stock, \$0.0001 par value, and one-half of one warrant	MAACU	The Nasdaq Stock Market LLC
Shares of Class A common stock included as part of the units	MAAC	The Nasdaq Stock Market LLC
Warrants included as part of the units, each whole warrant exercisable for one share of Class A common stock at an exercise price of \$11.50	MAACW	The Nasdaq Stock Market LLC
Indicate by check mark whether the registrant is an emerging growth compar	ny as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2	of the Securities Exchange Act of 1934.
Emerging growth company ⊠		
If an emerging growth company, indicate by check mark if the registrant has Section 13(a) of the Exchange Act.	elected not to use the extended transition period for complying with	any new or revised financial accounting standards provided pursuant to

#### Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 hereto and incorporated into this Item 7.01 by reference is the Analyst Day presentation that Roivant Sciences Ltd. ("Roivant") has prepared for use in connection with its Analyst Days, scheduled for June 25 and June 29, 2021 relating to the proposed business combination of Roivant and Montes Archimedes Acquisition Corp. ("MAAC"). The foregoing is being furnished pursuant to Item 7.01 and will not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise be subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

#### Forward Looking Statements

This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that are based on beliefs and assumptions and on information currently available. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," 'estimate," "predict," "project," "potential," "continue," "ongoing," "target," "seek" or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Any statements that refer to expectations, projections or other characterizations of future events or circumstances, including strategies or plans as they relate to the proposed business combination, are also forward-looking statements. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although each of MAAC and Roivant believes that it has a reasonable basis for each forwardlooking statement contained in this communication, each of MAAC and Roivant caution you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain. In addition, risks and uncertainties are described in the Registration Statement relating to the proposed business combination filed by Roivant with the SEC and other documents filed by MAAC or Roivant from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forwardlooking statements. Forward-looking statements in this communication include, but are not limited to, statements regarding the proposed business combination, including the timing and structure of the transaction, the proceeds of the transaction and the benefits of the transaction. Neither MAAC nor Roivant can assure you that the forward-looking statements in this communication will prove to be accurate. These forward-looking statements are subject to a number of risks and uncertainties, including, among others, the ability to complete the proposed business combination due to the failure to obtain approval from MAAC's stockholders or satisfy other closing conditions in the definitive agreement relating to the proposed business combination (the "Business Combination Agreement"), the occurrence of any event that could give rise to the termination of the Business Combination Agreement, the ability to recognize the anticipated benefits of the proposed business combination, the amount of redemption requests made by MAAC's public stockholders, costs related to the transaction, the impact of the global COVID-19 pandemic, the risk that the transaction disrupts current plans and operations as a result of the announcement and consummation of the proposed business combination, the outcome of any potential litigation, government or regulatory proceedings and other risks and uncertainties, including those included under the heading "Risk Factors" in the Registration Statement filed by Roivant with the SEC and those included under the heading "Risk Factors" in the annual report on Form 10-K for year ended December 31, 2020 of MAAC (as amended) and in its subsequent quarterly reports on Form 10-O and other filings with the SEC. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by MAAC, Roivant, their respective directors, officers or employees or any other person that MAAC and Roivant will achieve their objectives and plans in any specified time frame, or at all. The forward-looking statements in this communication represent the views of MAAC and Roivant, as applicable, as of the date of this communication. Subsequent events and developments may cause that view to change. However, while MAAC and Roivant may elect to update these forward-looking statements at some point in the future, there is no current intention to do so, except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing the views of MAAC or Roivant as of any date subsequent to the date of this communication.

#### Disclaimer

This communication is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the above-referenced business combination and does not constitute an offer to sell or a solicitation of an offer to buy any securities of MAAC or Roivant, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit
Number
99.1 Analyst Day Presentation
Description

### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

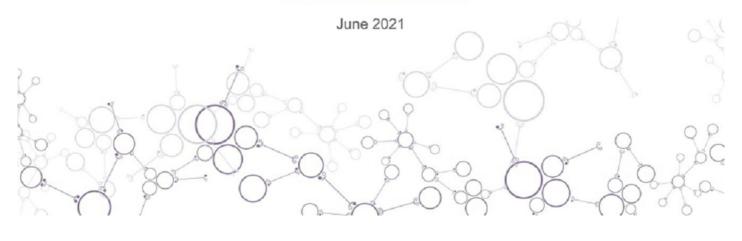
Dated: June 25, 2021

### MONTES ARCHIMEDES ACQUISITION CORP.

By: /s/ Maria C. Walker
Name: Maria C. Walker
Title: Chief Financial Officer



# **Roivant Overview**



# Statement of Limitations (1/2)

This investor presentation (this "Presentation") was prepared by Montes Archimedes Acquisition Corp. ("SPAC") and Rolvant Sciences Ltd. (the "Company") in connection with the proposed transactions (the "Business Combination") contemplated by the Business Combination Agreement, by and among SPAC, the Company and one of its affiliates.

It is not inlanded to form the basis of any investment decision or any other decisions with respect of the Business Combination. The information contained herein does not purport to be all-inclusive and none of the SPAC, the Company or any of their respective affiliates, directors or officers makes any representation or warranty, express or implied, as to the accuracy, completeness or reliability of the information contained in this Presentation.

This Procentation shall not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Business Combination

#### Forward Looking Statements

This Presentation may contain forward-looking statements for the purposes of the safe harbor provisions under The Private Socurities Litigation Reform Act of 1995 and other federal socurities laws. Forward-looking statements include, without limitation, statementa regarding the estimated furnament, financial position and financial impacts of the Suciness Combination, and the Business Combination, anticipated evanerable percentages of the combined company's stockholders following the potential transaction, and the business Combination, anticipated ownership percentages of the combined company's stockholders Combination, anticipated ownership percentages of the combined company's support of the Suciness Combination. Purpose of the Company's budgeneral day of the Suciness Combination in the Presentation contains forward-looking statements short represent opinions, expectations, beliefs, intentions, estimates offered in the Presentation contains forward-looking statements short represent opinions, expectations, beliefs, intentions, estimates of strategies regarding the future of SPAC and the Company and as a strategies of the Company and the strate

All forward-looking attainments are based to estimates and assumptions that are inherently uncertain and that could cause actual results to differ materially from expected results. Many of these factors are beyond SPAC3 and the Company's ability to Conform of predect. These risks anclude, but in ear on Initiated to (1) the occurrence of any event, including the conformation of any event, changes or the processing that may be instituted again the conformation of the submisses Combination; (3) the inability to complete the Business Combination on the training of the Business Combination on the submisses Combination on the submisses Combination (4) changes to the proposed structure of the Business Combination (5) the basility by the possibility that has been submissed to the submisses Combination (6) the activation of the Business Combination (6) that may be required or appropriate as a result of applicable less of company's interface (5) the ability to meet and maintain Residual stating standards following the consumeration of the Business Combination (7) (6) that appropriate the submisses Combination (7) (6) that appropriate as a result of the proposition of the submisses Combination (7) (6) that appropriate as a result of the proposition of the submisses Combination (7) (8) that appropriate (7) (8) that appropriate (8) the possibility that the Business Combination (7) (8) that appropriate as a result of the amountment and consumeration of the Business Combination (7) costs related to (7) the Company's inferior company's inferi

You are cautioned not to place undue reliance upon any forward-looking statements. Any forward-looking statements speaks only as of the date on which it was made, based on information available as of the date of this Presentation, and such information may be inaccurate or incomplete. In particular, and without limiting the foregoing, any information pertaining to immunovant, he required by the presentation is based solely on publicly available information as of June 1, 2021. SPAC and the Company undertake no obligation to publicly update or register any training the presentation as of June 1, 2021. SPAC and the Company undertake no obligation to publicly update or register any training to present the presentation as of June 1, 2021. SPAC and the Company undertake no obligation to publicly update or register any training to present the present training to present training training training to present training tra



# Statement of Limitations (2/2)

Participants in the Solicitation
SPAC and its directors and executive officers may be deemed participants in the solicitation of proxies from SPAC's stockholders with respect to the proposed Business Combination. A list of the names of those directors and executive officers and a description of their interests in SPAC is contained in SPAC's Registration Statement on Form S-1 as effective on October 6, 2020, which was filed with the SEC and is available free of charge at the SEC's web site at www sec gov. Additional information regarding the interests of such participants with the observable of proximal participants with the observable of security of SPAC in connection with the proposed Susiness Combination. A list of the names of such directors and executive officers may also be deemed to be participants in the solicitation of proxies from the stockholders of SPAC in connection with the proposed Susiness Combination. A list of the names of such directors and executive officers and information regarding their interests in the proposed Susiness Combination will be included in the definitive proxy statement / prospectus for the proposed Susiness Combination will be included in the definitive proxy statement / prospectus for the proposed Susiness Combination will be included in the definitive proxy statement / prospectus for the proposed Susiness Combination will be included in the definitive proxy statement of proximal proposed Susiness Combination will be included in the definitive proxy statement of proximal proposed Susiness Combination will be included in the definitive proxy statement of proximal proximal proposed Susiness Combination will be included in the definitive proxy statement of proximal pro



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### Introductions



Vivek Ramaswamy

Founder & Executive Chairman

Mr. Ramaswamy graduated summa cum laude in Biology from Harvard University in 2007 and began his career as a successful biotech investor where he oversaw investments in numerous companies, including those that helped develop curative treatment regimens for hepatitis C virus. He continued to work as an investor while earning his law degree from Yale Law School, where he was a Paul & Daisy Soros Fellow. Mr. Ramaswamy founded Roivant in 2014 and served as Chief Executive Officer until 2021.



Matthew Gline

Chief Executive Officer

Mr. Gline joined Roivant in 2016 and served as Chief Financial Officer from 2017 until 2021, when he was appointed our Chief Executive Officer. Prior to Roivant, Mr. Gline was a Vice President at Goldman Sachs, Fixed Income Digital Structuring, where he focused on technology and data strategy. Prior to Goldman Sachs, Mr. Gline was a co-founder of Fourthree, a risk analytics technology and consulting company. Mr. Gline earned his AB in Physics from Harvard University.



Jim Momtazee Chairman and CEO, Montes Archimedes Acquisition Corp

Mr. Momtazee is currently the Managing Partner of Patient Square Capital and has over 24 years of investment and acquisition experience. Prior to Patient Square Capital and Montes Archimedes Acquisition Corp, Mr. Momtazee spent over 21 years at KKR & Co., where he helped form the health care industry group in 2001 and ran the group for over 10 years. Mr. Momtazee currently serves on the Board of Directors of BridgeBio, PRA Health Sciences (lead independent director), and the Medical Device Manufacturers Association. He earned his BA and MBA from Stanford University.



### **Transaction Overview**

- · Roivant has entered into a definitive agreement to merge with Montes Archimedes Acquisition Corp. (MAAC)
- All-primary transaction values the pro forma Company at an enterprise value of \$5.0BN, and the Company would have a \$2.3BN pro forma net cash balance<sup>1,2,3</sup>
- The transaction will result in gross proceeds of \$631M, through a combination of:
  - MAAC's \$411M cash in trust1
  - · \$220M of committed PIPE financing
- Cash on hand will allow for runway through mid-2024 to fuel continued growth and investment initiatives<sup>1,2,4</sup>
- Current Roivant shareholders expect ~92% pro forma ownership<sup>1,3</sup>
- This transaction aligns priorities towards a successful long-term partnership that is focused on the Company's continued growth with:
  - Long-term lock-up for sponsor and key equityholders, including 50% locked-up for three years<sup>5</sup>
  - Conversion of some sponsor shares to earn-out shares that vest based on the Company's performance<sup>6</sup>
- · Closing expected in 3Q 2021



Source: Company filings and estimates. All figures and eas of December 31, 2020 unless otherwise notice. A Assumence of SPA condesprisons. 2. Assumps see SPAC or development, plandade soils, not expended to the condesprisons and the second section of the s

### **Montes Archimedes Investment Thesis**

- · Longstanding relationship with Roivant management team
- · Pattern recognition from experience with other successful biopharma platform companies



- Investment thesis regarding Roivant:
  - · World-class team
  - Innovative business model
  - · Demonstrable success

- · Proprietary technology assets
- · Promising pipeline
- · Platform for further Vant development



# Significant Potential Value in Roivant Platform

# Roivant has advanced pipeline and platform technology with multi-billion dollar valuation comparables





All product candidates at the Varia are investigational and subject to regulatory approval. There is no guarantee that the Varia will achieve valuations in line with the comparable companies included above. All trademarks are property of their respective owners. See page 75 for detail on Vant ownership.

1. Olazia acquired by Amper in November 2019. 2. Anazor acquired by Plizar in June 2016. 3. Market capitalizations for comparables as of May 28, 2021 unless otherwise indicated. 4. Momenta acquired by Johnson & Johnson in October 1.

# Roivant: Redefining "Big Pharma"

OUR MISSION	Improve the delivery of healthcare to patients by treating every inefficiency as an opportunity					
WHAT WE DO	Develop transformative medicines faster by building technologies and deploying talent in creative ways					
HOW WE DO IT	Leverage the Roivant platform to launch Vants – nimble companies focused on developing transformative medicines and technologies					
1. Create Value	2. Be Contrarian  3. Climb the Wall  4. Sweat the Details  5. Evolve or Die					



### What Have We Done?

### **Select Achievements**

- ✓ 8 positive Phase 3 trials of 9 total¹
- √ 3 FDA approvals from Vants launched by Roivant and owned by Sumitovant¹
- √ \$3BN upfront transaction with Sumitomo Dainippon Pharma (DSP)
- √ \$7BN EV transaction to merge Datavant and Ciox Health, creating largest neutral and secure health data ecosystem²



>40 medicines brought into development<sup>1</sup>

>20 Vants launched1

>800 employees across Roivant and Vants<sup>1</sup> >\$2BN consolidated cash balance<sup>5</sup>



1. Varia surranzy statistics include Arbulus, Dataward, and Sio, in which Roisent, Wan a non-controlling interest, and various undiscissed Variant Surranger Harburgh Varia Burnch, and approved ligures include Alliance Varia transferred to Sumitowant, a windy-owned subsidiary of Surranger Climpton Disrippon Pharmard, "Estimators,"). In Concentral 2013, 1987(111) and SPIRIT2 varies of the new preferred on Sumitor Surranger Variation Company based on the convenient price of the new preferred out, investment being made concurrently with closing of the preferred out, investment being made concurrently with closing of the preferred out, investment being made concurrently with closing of the preferred out, in the Verian Surranger Variation Variation Costs, and aggregate proceeds recoived at obtaining of the Surranger Variation Costs, and aggregate proceeds recoived at obtaining of the Surranger Variation Varia

# **8 Consecutive Positive Phase 3 Studies**

Study	Drug	Indication	Patients Enrolled	Geography	Topline Results		Primary p- value
PSOARING 1	Tapinarof	Psoriasis	510	1	August 2020	~	P < 0.0001
PSOARING 2	Tapinarof	Psoriasis	515	\$ 6 TA	August 2020	~	P < 0.0001
SPIRIT 1*	Relugolix	Endometriosis	638	34	June 2020	~	P < 0.0001
SPIRIT 2*	Relugolix	Endometriosis	623	***	April 2020	~	P < 0.0001
HERO	Relugolix	Prostate Cancer	934	李代	November 2019	~	P < 0.0001
LIBERTY 2	Relugolix	Uterine Fibroids	382	34	July 2019	~	P < 0.0001
LIBERTY 1	Relugolix	Uterine Fibroids	388	34	May 2019	~	P < 0.0001
EMPOWUR	Vibegron	Overactive Bladder	1,530	- A	March 2019	~	P < 0.001
MINDSET	Intepirdine	Alzheimer's Disease	1,315	<b>***</b>	September 2017	×	P > 0.05



Note: On Dec. 18, 2020, the PDA approved relixopilis for the treatment of solid patients with advanced prostate cannor. On Dec. 23, 2020, the PDA approved vibegron for the treatment of solid patients with owncord prostate cannor. On Dec. 23, 2020, the PDA approved vibegron for the treatment of solid patients with owncord behavior. Defensive the drugs noted solve on current popular or investigations and soligist to helding interval behavior approved. To December 2019 is read to corresponding proper services. Residency and vibegron on the behavior and the proper services. Residency and vibegron on the behavior and the proper services. Residency and vibegron of the proper services and vibegron of the proper services. Residency and vibegron of the proper services. Residency and vibegron of the proper services. Residency and vibegron of the proper services and vibegron of the property of th

# **Development Pipeline**

		Modality	Preclin	Phase 1	Phase 2	Phase 3
6	TAPINAROF Psoriasis   Dermavant	(E)				<b>•</b>
6	TAPINAROF Atopic Dermatitis   Dermavant	6			•	
6	CERDULATINIB Vitiligo   Dermavant				•	
Y	IMVT-1401 Myasthenia Gravis   Immunovant	P			•	
4	IMVT-1401 Warm Autoimmune Hemolytic Anemia   Immunovant	A.			•	
1	IMVT-1401 Thyroid Eye Disease   Immunovant	P .			•	
C)(	ARU-1801 Sickle Cell Disease   Aruvant	當			•	
0	AXO-LENTI-PD Parkinson's Disease   Sio Gene Therapies	ž			•	
0	AXO-AAV-GM1 GM1 Gangliosidosis   Sio Gene Therapies	當			<b>•</b>	
0	AXO-AAV-GM2 Tay-Sachs/Sandhoff Disease   Sio Gene Therapies	*			•	
Y	AB-729 Hepatitis B   Arbutus	**			•	
п	GIMSILUMAB COVID-19 Associated ARDS   Kinevant	1			•	
П	NAMILUMAB Sarcoidosis   Kinevant	P		•		
Ý	AB-836 Hepatitis B   Arbutus	æ°,		<b>&gt;</b>		
0	LSVT-1701 Staph Aureus Bacteremia   Lysovant	À		<b>&gt;</b>		
6	CERDULATINIB Atopic Dermatitis   Dermavant			<b>&gt;</b>		
6	DMVT-504 Hyperhidrosis   Dermavant	æ°		<b>&gt;</b>		
6	DMVT-503 Acne   Dermavant		<b>&gt;</b>			
0	ARU-2801 Hypophosphatasia   Aruvant	ğ	•			
	AFM32 Solid Tumors   Affivant	P	•			
**	CVT-TCR-01 Oncologic Malignancies   Cytovant	<b>©</b>	•			
20	Note: All drugs in current pipeline are investigational and subject to health authority approval.  SCIENCES	RNA Gene	Cell Topical	Small		





# Novel steroid-free topical tapinarof, if approved, could be uniquely positioned to transform two of the largest global immuno-dermatology markets

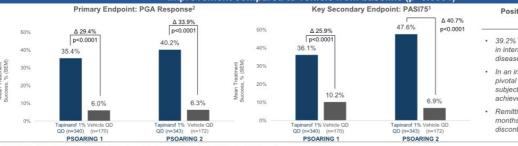
#### Value Added by Roivant Platform

- Leveraged platform expertise to expand IP with multiple patents expected to provide protection until at least 2036
- Hired leadership and provided investment that together delivered Phase 3 success

#### Potential To Transform the Treatment of Psoriasis and Atopic Dermatitis

- Once-daily, cosmetically elegant, non-steroidal cream that, if approved, could offer a favorable combination of treatment effect, safety, durability on therapy, and remittive effect
- · Psoriasis and atopic dermatitis affect an estimated 8M and 26M patients in the US, respectively
- · Potential to be used across mild, moderate & severe plaque psoriasis, including sensitive areas

# Psoriasis Phase 3: Statistically significant improvement in PGA score of clear or almost clear with a minimum 2-grade improvement compared to vehicle from baseline (p<0.0001)<sup>1</sup>



#### Positive Data from Long-Term Extension Study:

- 39.2% (299/763) of subjects included in interim analysis achieved complete disease clearance (PGA=0)
- In an integrated analysis including the pivotal trials and extension, 63.5% of subjects achieved PASI75 and 44.2% achieved PASI90<sup>4</sup>
- Remittive benefit of approximately four months observed following treatment discontinuation<sup>5</sup>



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# Only one-time potentially curative gene therapy for sickle cell disease with demonstrated ability to engraft with reduced intensity conditioning (RIC)

### Value Added by Roivant Platform

- Longstanding Roivant relationship with CCHMC enabled initial asset license and strong academic-industry partnership
- Manufacturing process improvements have enabled increased hemoglobin F expression and vaso-occlusive event (VOE) reduction

### Well-Positioned Against Competitors<sup>1</sup>







~\$2BN market cap Oxbryta approved Chronic therapy ~\$9BN market cap Developing CTX001 Requires myeloablation ~\$2BN market cap Developing LentiGlobin Requires myeloablation

ARU-1801 is only product candidate clinically shown to engraft with only an RIC regimen

Preliminary clinical data from ongoing Phase 1/2 trial of ARU-1801 demonstrate potential to deliver durable, meaningful VOE reductions to patients with sickle cell disease<sup>2</sup>

		Hospitalized VOEs			Total VOEs			
		Pre-treatment (24 mo)	Post-treatment (24 mo)	Reduction (%)	Pre-treatment (24 mo)	Post-treatment (24 mo)	Reduction (%)	
٦. [	Patient 1	7	1	86%	41	3	93%	
Process I	Patient 2	1	0	100%	20	3	85%	
Process II	Patient 3	6	0 at 12 mos	100%	12	0 at 12 mos	100%	

- Process I has shown durable engraftment to 36+ months in Patients 1 and 2
- Process II has shown improved product profile with Patient 3 showing highest HbF and F-cells to date



Note: All drugs in current pipeline are investigational and subject to health authority approval. All trademarks are properly of their respective owners. VCN = vector copy number.

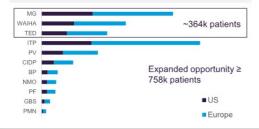
1. Approximate market capitalizations as of May 28, 2021. There is no guarantee that Aruvant will achieve a valuation in line with these companies.



# Rapidly initiated multiple Phase 2 trials to develop anti-FcRn antibody IMVT-1401 as a best-in-class or first-in-class subcutaneous injection

#### Value Added by Roivant Platform

- Identified and licensed drug from HanAll Biopharma and expanded potential patient reach by selecting three initial indications with first- or best-in-class potential
- Funded and ran key Phase 1 pharmacodynamic trial, positioning for successful public listing via reverse merger
- Recruited key executive leadership, and board of directors led from inception by Roivant employee



#### **Clinical Results to Date**

- Myasthenia Gravis¹: 60% responder rate on the MG-ADL<sup>II</sup> vs 20% for placebo, and 3.8-point mean improvement on myasthenia gravis activities of daily living (MG-ADL, p=0.039)
- Warm Autoimmune Hemolytic Anemia: 1 of 3 patients dosed ≥ 11 weeks achieved an increase in hemoglobin well over 2 g/dL from baseline, which was maintained during treatment
- Thyroid Eye Disease: In Phase 2a, 57% of patients improved by ≥ 2 points on clinical
  activity score (CAS), and 43% of patients were both proptosis responders\* and CAS
  responders\*\*; efficacy results in Phase 2b, which was terminated early, were inconclusive

# Resuming Clinical Development Following Observed Increases in Cholesterol and LDL

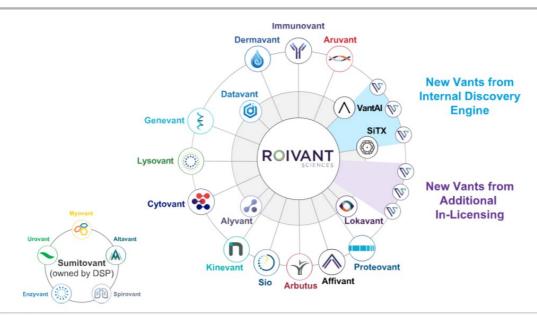
- In February 2021, Immunovant voluntarily paused dosing in ongoing clinical studies to investigate observed elevated cholesterol levels
- Program-wide data review suggests that lipid elevations are predictable, manageable, and appear to be driven by reductions in albumin, with the 255 mg dose resulting in modest changes to LDL and albumin with potent knockdown in IgG
- The increases in LDL and reductions in albumin were reversible upon cessation of dosing, and no major adverse cardiovascular events have been reported to date



Note: All drugs in current pipeline are investigational and subject to health authority approval. All Indehmarks are properly of their respective owners.

Based on interim analysis of 15 trial participants. After the Interim analysis are additional the patients expected and were renderized. \*Mo-ADL responders defined as patients showing ≥ 2-point improveme 'Proptosis responders improved ≥ 2mm; in study eye without significant deterioration in fellow eye. "CAS responders achieved a total CAS soore of to r f.

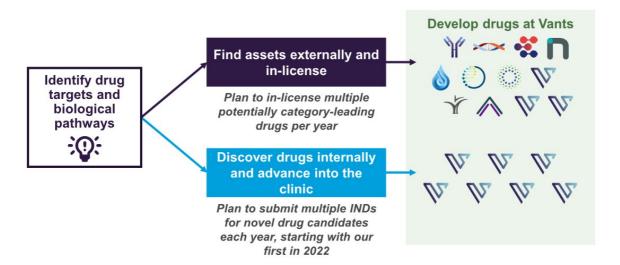
# Vant Model Enables Rapid Scaling





All trademarks are property of their respective owners. Altavant. Enzyvant. Myovant. Spirovant, and Urovant were transferred to Sumitovant, a wholiv-owned subsidiary of Sumitomo Dainippon Pharma. in December 2019.

# The Roivant Model for Drug Discovery and Development





### **Roivant Approach to Drug Discovery**



# Target Selection

"Investment lens" for target identification, powered by computational tools and interdisciplinary team of R&D experts, investors



### Degrader Expertise

Novel ligands, multi-year partnership with premier academic lab and modality-specific medicinal chemistry expertise



### **VantAl**

Leading machine learning-based in silico platform for design and optimization of protein degraders, continuously fed by experimental results from across



### **SiliconTx**

Leading computational physics platform for in silico design and optimization of small molecule therapeutics, integrated with proprietary supercomputing cluster



### **Wet Labs**

In-house facility fully equipped for biophysics, synthetic chemistry, crystallography and biology; tightly integrated with in silico capabilities to augment simulations and generate high resolution crystal structures



### **Development**

Track record of success in clinical trial execution; ability to design, initiate and complete trials rapidly

### Small Molecule Discovery Engine

### Leader in Computational Drug Discovery

Unique combination of computational physics and machine learning based platforms for *in silico* design of small molecules



#### Leader in Degrader Discovery

Initial pipeline of degraders for targets spanning oncology, immunology and neurology, with first Phase 1 initiation expected in 2022



### **Leading Computational Discovery Capabilities**



Woody Sherman, Chief Computational Scientist

Internationally renowned pioneer in computational chemistry; 13-year career as technical and scientific leader at Schrödinger before joining Silicon Therapeutics / Roivant



# Computational Physics

Peer to Schrödinger's FEP+ for speed and accuracy of binding free energy calculations

**Distinctive Roivant Advantage** 

Simulations powered by proprietary supercomputing cluster and restrained by experimental biophysics data create sustainable advantage in capabilities

# Sample Proprietary in silico Assays

- Predict binding affinity of a ligand and a protein
- Predict conformational dynamics of a protein as it shifts from active to inactive state
- · Identify binding sites on a protein



Machine-learning models for protein degradation and ADMET prediction trained on >5 years of proprietary degrader-specific experimental data and millions of carefully curated protein stability datapoints

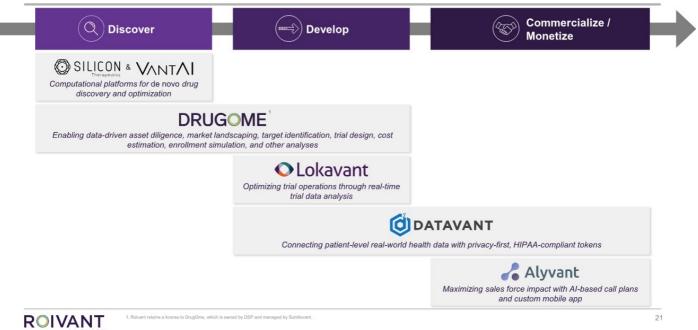
- Graph representations of known protein-protein interactions to design new degraders that can effectively stabilize target-E3 interfaces
- Ubiquitin-proteasome system map to identify degron motifs



# **Computational Discovery and Degrader Pipeline**

	Target	Discovery	Lead Optimization	IND-Enabling
Oncology	AR			<b>&gt;</b>
	STAT3		<b>&gt;</b>	
	BRD4		<b>&gt;</b>	
	CBP/P300		<b>&gt;</b>	
	SHP2	<b>&gt;</b>		
	SMARCA2/4	<b>&gt;</b>		
	KRASG12D	<b>&gt;</b>		
	WRN	<b></b>		
	JAK2-617F	<b>&gt;</b>		
	CRAF	<b>&gt;</b>		
	HIF2A	<b></b>		
	ADAR1	<u> </u>		
	Undisclosed Additional Programs	<b>&gt;</b>		
Neurology	mHTT	•		
	Undisclosed Additional Programs	<b>&gt;</b>		
Immunology	STING	•		
	NLRP3	<b>&gt;</b>		
	112.11 0			

# Roivant's Integrated Technologies Underpin an End-to-End Biopharma **Platform**



# Leadership Team Positioned to Execute on Our Vision



Vivek Ramaswamy Founder & Executive Chairman



Matthew Gline
Chief Executive Officer



Eric Venker, MD, PharmD

Chief Operating Officer



Roger Sidhu, MD Head of R&D & Chief Medical Officer



Mayukh Sukhatme, MD
Chief Investment Officer



Frank Torti, MD Vant Chair



Benjamin Zimmer
President, Roivant Health

pharma















All trademarks are property of their respective owners

FOUNDERS FUND

Dermavant				



### Building a leadership position in immuno-dermatology



#### Todd Zavodnick

CHIEF EXECUTIVE OFFICER

Former CCO and President at Revance Therapeutics; global leadership positions at ZELTIQ and Galderma



Philip M Brown, MD, JD

CHIEF MEDICAL OFFICER

Former Head of Global Pharmaceutical Development at Galderma; Senior Vice President of Clinical Development at Lexicon Pharmaceuticals



CHIEF COMMERCIAL OFFICER CHIEF COMMERCIAL OFFICER
Former Vice Prescription
Business at Galderma; Senior Principal,
Core Access Group and Executive
Director, Managed Markets and
Contracting at Medicis; various
commercial leadership roles at Pfizer



#### David Rubenstein, MD, PhD

CHIEF SCIENTIFIC OFFICER

Former VP, Discovery and Clinical Development at GlaxoSmithKline; Louis C. Skinner Jr. Distinguished Professor of Dermatology at University of North Carolina Chapel Hill

- · Lead asset tapinarof, if approved, could be uniquely positioned to transform two of the largest global immunodermatology markets, psoriasis and atopic dermatitis
- Tapinarof is a novel, once daily, cosmetically elegant, steroid-free TAMA topical cream with positive Phase 3 data in psoriasis, including extension data supporting long-term use
- Topicals serve as the foundation of dermatologic treatment, representing 83% of all US prescriptions written by dermatologists in 2020
- $\bullet \ \ \text{If approved, tapinar of could be the first novel topical the rapy approved by the FDA for plaque psorias is in over the results of the results of$ 20 years and be used across mild, moderate, and severe plaque psoriasis, including sensitive areas
- Multiple patents for tapinarof expected to provide IP protection until at least 2036
- Rich pipeline with novel and differentiated MOAs pursuing the largest indications in medical dermatology

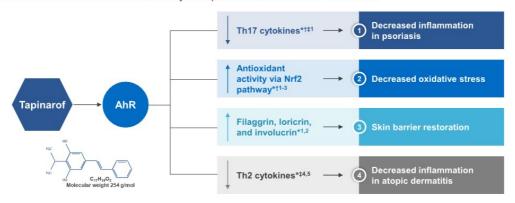
Preclinical	Phase 1	Phase 2	Phase 3	Next Key Milestone
TAPINAROF Psoria	sis			FDA approval decision expected mid-2022
TAPINAROF Atopic	Dermatitis			Phase 3 initiation expected H2 2021
CERDULATINIB Vit	iligo			Phase 2a data
CERDULATINIB Ato	opic Dermatitis			Phase 2a protocol in development
DMVT-504 Hyperhid	rosis			Phase 2b protocol in development
DMVT-503 Acne Vul	Igaris			Preclinical studies ongoing



# **Tapinarof Overview**

# Novel, once daily, cosmetically elegant, steroid-free therapeutic aryl hydrocarbon receptor modulating agent (TAMA) topical cream

TAMA is designed to inhibit two pro-inflammatory pathways implicated in psoriasis and atopic dermatitis; AhR modulation by tapinarof also increases antioxidant activity and promotes skin barrier restoration





\*Observed in vitro. †Observed ex vivo. †Observed in mice models. ARR, anyl hydrocarbon receptor. MrZ, nuclear factor enythroid 2-related factor 2: TAMA. therapeutic anyl hydrocarbon receptor modulating agent, Th. Thelper cell. 1. Smith SH et al. J Inv Dermato2017;137:2110-2119. 2. Furue M et al. J Dermatological Sci. 2015;80:83-88. 3. Tauji G et al. J Invest Dermatol. 2012;132:59-88. 4. Dermavant DOF [DMVT-505 This Polarization, Apr 2015]. 5. Dermavant DOF [DMVT-505 This Polarization].

# **Tapinarof Targets Two of the Largest Markets in Immuno-Dermatology**

Psoriasis and atopic dermatitis markets projected to reach ~\$25BN in the US and ~\$37BN globally by 2026





Evaluate Pharma Data: Global Psoriasis and Atopic Dermatitis Prescription Drugs Market and Forecast 2019 – 2026 (excluding Skin Cancer); Psoriasis Indication Profile, USA Market Analysis; Atopic Dermatitis Indication Profile, USA

### **Tapinarof for Psoriasis**

# Tapinarof has the potential to be the first novel topical therapy approved by the FDA for plaque psoriasis in over 20 years

### **Psoriasis Overview**

- Chronic, inflammatory disease with skin lesions characterized by red patches and plaques with silvery scales
- · Affects an estimated 8M people in the US1
- Approximately 80% of US patients have mild to moderate disease<sup>2</sup>



### **Tapinarof Positioning in Psoriasis**

- Continual and long-term treatment with topical corticosteroids, the most commonly prescribed first-line topical agents for plaque psoriasis treatment, carries the risk of a variety of significant side effects, such as skin atrophy, striae (stretch marks), and telangiectasia (spider veins), among others<sup>3-8</sup>
- The use of biologics has been limited by concerns with systemic side effects and high costs, and they are often limited to moderate-to-severe patients, which comprise the smallest percentage of the affected populations
- Tapinarof has the potential to treat all disease severities (mild, moderate, and severe) and to be used as a chronic therapy due to its minimal systemic absorption and favorable safety and tolerability findings to date



1. National Psortains Foundation (Portains Foundation (Portains Foundation) (Portains Fo

# **Tapinarof Market Opportunity in Psoriasis**

			Potential for co-prescription with tapinarof				
	TCS	Vitamin D / Combos / Retinoids	Biologics	Otezla	Other Oral		
Annual Scripts (2020)	~2.35M	~508K	~1.05M	~258K	~241K		
Tapinarof Relative Value Proposition	and safety concerns, appli limits on duration of therap  TCS are commonly used a psoriasis but carry FDA claduration and location of us	by the first-line therapy ass labeling restricting e tited to intermittent treatment ding to frequent disease	Use of biologics limited by concerns with systemic side effects, high cost, and reimbursement and access restrictions	Oral therapies are fur moderate-to-severe p  Oral therapies also ha effects and have not a level of efficacy as bid	soriasis patients ave significant side achieved the same		



Source 1. Symphony PrescriberSource May 2018 — October 2020.

Market Notes 1. Market Includes Dem only Tiss for all product groupings. 2. Symphony PrescriberSource includes grojected mail service data

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Market Definition Notes 1. 10.25. Applied 7.5% factor on TCS volume, derived from IQVA NOTI. 2. Vitamin I, J. Company (Intelligence Services) (I

### Phase 3 PSOARING Program – Study Design

### Over 1,000 patients enrolled in two identically designed pivotal trials followed by long-term openlabel extension study

Long-term Open Label Extension<sup>†</sup> **Double-blind Treatment** (12 weeks) (40 weeks) Tapinarof 1% QD PSOARING 1 **Patients with Plaque** R 2:1 (DMVT-3001) **Psoriasis** n = 510<sup>1</sup> > Aged 18-75 years old > PGA score ≥2\* Tapinarof 1% QD PSOARING 2 ≽ BSA ≥3% - ≤20% R 2:1 (DMVT-3002)  $n = 515^2$ 

PSOARING 3 Long-term Extension (LTE) Off-(DMVT-3003) Treatment  $n = 763^3$ Withdrawal & Re-treatment

#### Primary endpoint:

> PGA score of 0 (clear) or 1 (almost clear) & ≥2-grade improvement from baseline at Week 12

#### Secondary endpoints:

- > Proportion of patients achieving PASI75 from baseline at Week 12
   > Proportion of patients achieving PASI90 from baseline at Week 12

- > PGA score 0 or 1 at Week 12
   > Mean % change in total BSA from baseline at Week 12

#### Open Label Extension:

Patients entering open label extension remain on treatment with tapinarof 1% QD until a PGA score of 0 is achieved

#### Re-treatment criteria:

Patients with psoriasis disease worsening, defined as PGA score ≥2, enter retreatment with tapinarof 1% QD until a PGA of 0 is achieved



29

Follow-Up

(4 weeks)

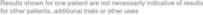
# Phase 3 PSOARING Program - Primary Efficacy Results

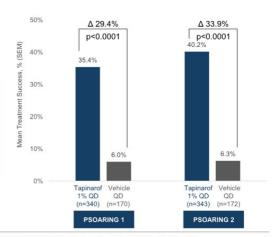
#### **Primary Endpoint Achieved**

# PGA Score of 0 or 1 and ≥2-Grade Improvement from Baseline at Week 12 (ITT, MI)

- In two replicate Phase 3 trials, PSOARING 1 and PSOARING 2, tapinarof demonstrated superior PGA response rates at week 12 as evidenced by statistically significant difference vs. vehicle (p<0.0001 and p<0.0001)<sup>1,2</sup>
- 35.4% and 40.2% of patients achieved treatment success at week 12 with tapinarof 1% cream QD vs. 6.0% and 6.3% for vehicle in PSOARING 1 and 2, respectively¹
- 20% and 22% of patients achieved a PGA response at week 16 in trials of oral Otezla vs. 4% and 4% for placebo, respectively<sup>3,4</sup>
- Based on the clinical data generated to date, we have submitted an NDA for tapinarof for the treatment of plaque psoriasis to the FDA









GA and PASI are global efficacy assessments. Example of one representative target lesion of one tapinarof readed patient from the PSOARING 1 clinical trial. PASI, Psoriasis Area and Severity Index; ITT, Intention-to-treat, MI, multireputation, SEM, standard error of mean; OD, once disky.

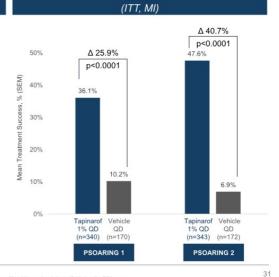
Proportion of subjects who are histories of Biologista (Biologista) Assessment (PGA) across of clear (1) or almost clear (1) with a minimum 2-protein interpressment from Reselling at Week 12, 2. Purelism has a protein for the proportion of subjects who are histories of the processing a subject to the processing and the processi

Proportion of subjects with active end a Physician Guoda Assessment (PGA) score of clear (i) or almost clear ()) with a minimum 2-grade improvement from baseline at Press 12, 2, 2 P-value based upon Journal-Marine-Haeriszeri Applies staffilled by PGA score, 3, Official prescribing information, 4, No head-to-head brials of tapinarof have been conducted against any poortasis treatment. Trials conducted at different points in time using different brial designs an ifferent patient populations.

# Phase 3 PSOARING Program - Key Secondary Efficacy Results

#### **Secondary Endpoint Achieved**

- PASI75 at week 12 was statistically significantly higher in both tapinarof groups compared with vehicle groups (p<0.0001 and p<0.0001)<sup>1,2</sup>
- 36.1% and 47.6% of patients achieved PASI75 at week 12 with tapinarof 1% cream QD vs. 10.2% and 6.9% for vehicle
- The PASI assessment is a more quantitative assessment of disease activity relative to the PGA and provides additional insight into a drug's impact on disease modification
- Similar to what was observed with PGA, evaluating reduction in the burden of disease via a PASI assessment confirms rapid onset of action with separation of tapinarof from vehicle cream control at week 2, and statistically significant differences were noted as early as week 4 and at each evaluation thereafter



PASI75 from Baseline at Week 12



GA, Physician Global Assessment; ITT, intention-to-freat, Mi, multiple imputation; SEM, standard error of mean; QD, one cally,
Proportion of subjects with 2755 improvement in pooriasis area and severity index (PAS) from baseline. 2 P-value based upon Cochran-Mantel-Haenszel analysis stratified by baseline PGA score

.

### **Phase 3 PSOARING Safety Profile**

### Favorable safety results observed with low rate of study discontinuation due to AEs

#### > AE profile consistent with previous studies

- Most common AEs (≥5%) were folliculitis, nasophyngitis, and contact dermatitis
- Low rate of study discontinuation due to AEs on tapinarof (5.6% in PSOARING 1 and 5.8% in PSOARING 2)
- · Treatment-related TEAEs >1% were folliculitis, contact dermatitis, headache, pruritus, and dermatitis

#### > Majority of AESIs were mild or moderate

• Very low trial discontinuation rate due to AESIs: ≤1.8% due to folliculitis, ≤2% due to contact dermatitis, and ≤0.6% due to headache

#### > No clinically relevant effects or trends on laboratory values or vital signs

- · Low potential for drug-drug interactions
- · No requirements for dose titration or lab monitoring
- Tapinarof could not be detected in >93% of PK samples from a subset of the study population, even with a highly sensitive assay

#### No treatment-related SAEs

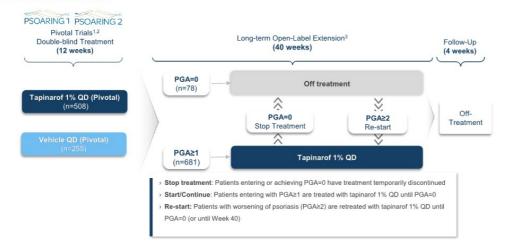
- · Majority of patients elected to remain in the study and continue on treatment following event
- 9 of the 16 patients who experienced an SAE elected to roll over into the long-term extension study



AE adverse event: TEAE, treatment emergent adverse event; AESI, adverse event of special interest; SAE, severe adverse event.

## Phase 3 PSOARING Extension – Study Design

# Over 90% of eligible patients who completed the pivotal trials elected to roll over into the long-term open-label extension trial





Note: 4 patients had a missing PGA at baseline. BSA, body surface area; PAS, Poorsais Area and Severify Index; PGA, Physician Global Assessment, CD, once daily 1. Clinicatrists, gov. NCT0996359. 2. Clinicatrists gov. NCT0996359.

### Phase 3 PSOARING Extension – Summary Interim Results

Pre-specified interim analysis contains all data from all patients (n=763) as of the cutoff date and includes data over the 44-week study duration

#### **Treatment Effect**

- 39.2% (299/763) of PSOARING 3 patients achieved complete disease clearance (PGA score=0)
- 57.3% (298/520) patients who entered the study with a PGA≥2 achieved a PGA=0 or 1 at least once during the study
- An integrated analysis of efficacy was performed with data from PSOARING 1, 2 and the PSOARING 3 interim analysis:
  - PASI751 was achieved in 63.5% of subjects
  - PASI902 was achieved in 44.2% of subjects

#### Safety and Tolerability

- No new safety signals observed regardless of duration of therapy
- Similar adverse event profile as observed in pivotal studies
- Well tolerated in all skin locations with extended exposure, including sensitive areas such as face, intertriginous areas, and genitals
- The interim analysis population exceeds ICH requirements for chronic use labeling

#### **Durability and Remittive Effect**

- All efficacy endpoints show continued improvement beyond 12 weeks
- No loss of treatment effect was observed over time even with intermittent use
- Approximately 4 months median duration of disease control observed after discontinuation of therapy<sup>3</sup>



1. Proportion of subjects with >75% improvement in psoriasis area and severity index (PASI) from baseline 2. Proportion of subjects with >90% improvement in psoriasis area and severity index (PASI) from baseline 3. For subjects

### **Atopic Dermatitis**

#### Tapinarof offers novel mechanism of action for atopic dermatitis market

#### **Atopic Dermatitis**

- Chronic, inflammatory skin disease characterized by dry, itchy skin, with a complex pathophysiology involving genetic, immunologic and environmental factors
- Affects more than 9.6 million children and about 16.5 million adults in the US<sup>1</sup>
- Approximately 89% of adult patients have mild to moderate atopic dermatitis<sup>2</sup>
- · Occurs most frequently in children3



#### **Unmet Need In Atopic Dermatitis**

- Safety concerns and risk of systemic side effects limit topical corticosteroid long-term use, particularly in children<sup>4</sup>
- Oral and biologic therapies are expensive and reserved for patients with significant disease burden due to their potential systemic side effects
- Tapinarof has the potential to fill the need for a treatment option for atopic dermatitis based on its favorable safety, tolerability, and symptom resolution findings to date



National Eczema Association 2, Asthma and Allergy Foundation of America, 3. Eichenfield, LF. Guidelines of care for the management of atopic dermatitis," 4, Coondoo, A. et al. "Side-effects of topical steroids: A long overdue revisit."

# **Tapinarof Market Opportunity in Atopic Dermatitis**

	TCS	тсі	Eucrisa	Dupixent
Annual Scripts (2020)	~16.4M	~996K	~352K	~344K
Tapinarof Relative Value Proposition	Continual long-term TCS use has the potential to cause significant side effects, such as skin atrophy  HCPs and patients are limited to intermittent treatment cycles of TCS therapy, leading to frequent disease flares and recurrence of disease	TCIs are an additional non- steroidal option for the topical treatment of atopic dermatitis  TCI use limited by safety concerns including boxed warnings of malignancy (e.g., skin and lymphoma) reported in patients treated with topical calcineurin inhibitors	Topical PDE4 inhibitors developed to treat atopic dermatitis have been associated with side effects including application site burning and stinging	Biologic therapies often limited to moderate-to-severe psoriasis and atopic dermatitis patients, which comprise the smallest percentage of the affected populations Biologics use limited by concerns with systemic side effects, high cost, and reimbursement and access restrictions



Source: 1. Symphony Prescriber/Source May 2018 – October 2020.

Market Notes: 1. Symphony Prescriber/Source includes projected mail service data

Market Notes: 1. Symphony Prescriber/Source includes projected mail service data

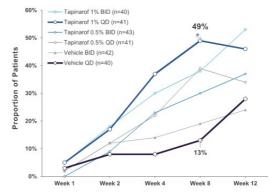
Market Definion Notes: 1 TCS Applied 39% factor or TCS Julium derived from IDVIA NDTI (Diagnosis Codes: 691801 691802 691803 692901 692902 692904 692905 692907 692908 692909 2 TCI: Pronosic El

### **Phase 2b Tapinarof Atopic Dermatitis Trial**

- Percentage of patients achieving treatment success at week 12 was much higher than vehicle cream for both tapinarof concentrations, with a robust dose response
- 53% of patients who applied tapinarof cream 1% BID and 46% of those who applied it QD were considered a treatment success at week 12, vs. 24% and 28% for vehicle cream BID and QD, respectively
- At week 12, 60% and 51% of patients treated with tapinarof cream 1% BID and QD, respectively, achieved secondary endpoint EASI75
- The treatment effect across adults and adolescents was observed to be consistent
- Observed to be well-tolerated, with the majority of treatment-emergent adverse events reported as mild or moderate.

## IGA Score 0 or 1 and ≥2-Grade Improvement at Week 8 Primary Endnoint was at 12 Weeks: Assessed in ITT Population

Primary Endpoint was at 12 Weeks: Assessed in ITT Population (NRI Analysis)





"Difference vs. vehicle cream is statistically significant at p=0.05 level (the 95% confidence interval excludes 0). NRI analysis to account for higher dropout rates in vehicle group. BID, twice daily, IGA, Investigator Global Assessment, ITT,

#### **Promising Earlier-Stage Pipeline**

# Cerdulatinib

- Novel topical dual JAK and Syk inhibitor being developed as a potential treatment option for vitiligo and other inflammatory skin conditions such as atopic dermatitis
- · Vitiligo Phase 2a initiated in 2019; topline results met the primary endpoints of safety and tolerability
- Multiple published reports suggest that JAK inhibitors alone might be effective for the treatment of vitiligo, and suppression of antigen-presenting cell activity by Syk inhibition has the potential to prevent initiation and stimulation of the autoimmune response that may contribute to the pathogenesis of vitiligo
- In a mouse model of vitiligo, oral cerdulatinib showed a significant decrease in vitiligo scores compared with vehicle, prevented epidermal depigmentation in the mice, and was associated with a significant reduction of melanocyte-specific T cells in skin tissues
- Demonstrated reductions in atopic dermatitis disease activity and evidence of drug-target engagement via biomarkers in Phase 1 study, with no serious adverse events reported or study discontinuations

DMVT-504

- Oral combination of an immediate-release muscarinic antagonist, oxybutynin, with a delayed-release muscarinic agonist, pilocarpine
- Under development for the treatment of primary focal hyperhidrosis, a condition characterized by excessive sweating beyond what is physiologically required by the body or what is expected given the local environment and temperature
- · Designed to mitigate dry mouth typically observed with anticholinergic therapies for better long-term tolerability

DMVT-503

- · Topical DGAT1 inhibitor being developed for the treatment of acne vulgaris
- Conducting a preclinical mouse model study to explore the potential for DMVT-503 to induce dose-dependent atrophy of sebum-producing sebaceous glands, a similar effect to and potential biomarker of isotretinoin efficacy



Immunovant				

#### **Immunovant Overview**



#### **Enabling normal lives for patients with autoimmune diseases**



## Pete Salzmann, MD CHIEF EXECUTIVE OFFICER

Former Global Development Leader in Immunology, Head of US Immunology, in addition to various other leadership roles at Eli Lilly



#### Bill Macias, MD, PhD

CHIEF MEDICAL OFFICER Former CEO at Focus Biomedical Consulting and interim CMO for Promethera Biosciences; multiple global development leadership roles in the Biomedicines Business Unit at Eli Lilly



#### Pamela Connealy

Pameia Connealy
CHIEF FINANCIAL OFFICER
Previously CFO and COO of nonprofit
organization Kiva, Global Head of Talent at
the Bill & Melinda Gates Foundation; CFO
of R&D and Global Head of Procurement at
Genentech



#### Julia G. Butchko, PhD

Julia G. BUICHKO, PHD
CHIEF DEVELOPMENT AND
TECHNOLOGY OFFICER
Former Chief of Staff for the Immunology and
Neurosciences businesses at Eli Lilly, as well
as VP of Eli Lilly's Cnoclogy Project
Management and Clinical Development teams

- Developing IMVT-1401, a novel, fully human monoclonal antibody inhibiting FcRn-mediated recycling of IgG
- Designed from inception to be a potentially class-leading subcutaneous injection
- Pipeline-in-a-product with attractive market in autoimmune diseases mediated by pathogenic IgG
- Strategy for IMVT-1401:
  - Be best-in-class in target indications where anti-FcRn mechanism has already established clinical proof-
  - · Be first to study FcRn inhibition in target indications with clear biologic rationale and no known in-class competition
- Patent estate expected to provide composition-of-matter and method-of-use protection until at least 2035 in the US and other foreign jurisdictions Phase 2

Preclinical	Phase 1	Phase 2	Phase 3	Next Key Milestone
IMVT-1401 Myasthenia (	Phase 3 initiation expected in late 2021 or early 2022			
IMVT-1401 Warm Autoin	nmune Hemolytic Anemia			Phase 2a restart in late 2021 or early 2022
IMVT-1401 Thyroid Eye	Disease			Study start TBD
IMVT-1401 Indication #4				Two new indications expected to be announced in
IMVT-1401 Indication #5				H1 2022



#### Roivant Intention with Respect to Immunovant

#### On March 8, Roivant filed a 13D/A disclosing the following:

- Roivant intends to propose to Immunovant that Roivant and Immunovant evaluate a potential transaction pursuant to which Roivant or an affiliate would acquire the minority interest in Immunovant
- Roivant expects that any potential transaction would be at a per share price representing a premium to current trading levels, consistent with similar precedent transactions in the life sciences industry involving acquisitions of minority interests by majority shareholders, with the mix of cash or equity consideration to be mutually determined by Roivant and Immunovant
- As Immunovant's controlling shareholder, Roivant has received nonpublic information about Immunovant and its lead product candidate
- No assurances can be given that a proposal will be made to Immunovant, that any transaction with Immunovant will be consummated or that Roivant will complete a public listing

In response to the filing, Immunovant's board of directors formed a special committee consisting of independent directors to be prepared to evaluate and negotiate any such proposal from Roivant or other parties



## Attractive Market in Autoimmune Diseases Mediated by Excess IgG

#### FcRn inhibition lowers IgG levels, suggesting utility in multiple autoimmune diseases

Illustrative list of autoimmune diseases driven by pathogenic IgG and their estimated prevalence (2020)







fole: List of diseases is illustrative only and does not represent our targeted indications (for more information, see immunovant's most recent Annual Report on Form 10-K filed with the SEC on June 1, 2021), MG. Myasthenia Gravis;

(ARHA: Warm Autoimmune Henolytic Ameria; TEC: Thypiod Eye Disease; TIP Idiopathic Thromboortoperine Purpura; PV. Pempiligas Vulgaris; CIDP. Chronic Inflammatory Demyelinating Polyneuropathy; BP. Bullous Pemphigoid, NMO

unannealitis Gotton P-Pemphigoid Expanse; GBS. Guillaid-Barel Servinderse Pulls III. Pul 2249: Marbranouros Neberboadstiv.

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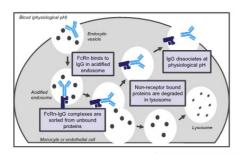
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## IMVT-1401 Promotes IgG Degradation<sup>1</sup>

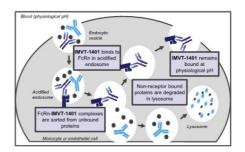
#### FcRn Prolongs the Half-Life of IgG<sup>2</sup>

- FcRn intercepts IgG, which would otherwise be degraded in lysosomes
- The FcRn–IgG complex is then recycled to the cell surface and free IgG is released back into circulation



# Inhibiting FcRn Promotes IgG Degradation<sup>2</sup>

- IMVT-1401 binds to FcRn, thereby preventing it from recycling IgG antibodies back to circulation
- As a result, IgG is increasingly delivered to lysosomes for degradation







Collins 1, and Jones L, et al. IMVT-1401 (RVT-1401). A Novel Anti-Ficht Monoclonal Antibody, Wiss Well Treated in Healthy Explicate and Reduced Serum (pG Following Subculameous or Intravenous Administration. Presented at merican Academy of Neurology Annual Conference, 2019. Program #87-2079. 2 Derry c, 4 al. Ficht: the near Forespire Conness of age. Nature Reviewee Immunology, 2007.

#### **Recent Developments**

After voluntarily pausing dosing in ASCEND GO-2 and ASCEND-WAIHA trials of IMVT-1401 due to elevated total cholesterol and LDL levels, Immunovant plans to resume clinical development of IMVT-1401 in MG and WAIHA as well as announce two additional indications in the next year

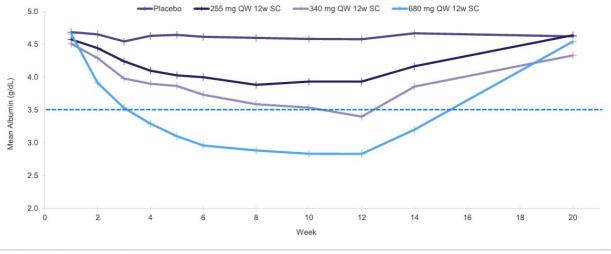
- · In Immunovant's ASCEND GO-2 trial, lipid parameters were assessed at baseline, at 12 weeks, and at week 20 following eight weeks off study drug
- · Based on preliminary, unblinded data, median LDL cholesterol at week 12:
  - · Increased by approximately 12 mg/dL in the 255 mg dose group (corresponding to an increase from baseline of approximately 15%)
  - · Increased by approximately 33 mg/dL in the 340 mg dose group (corresponding to an increase from baseline of approximately 37%)
  - · Increased by approximately 62 mg/dL in the 680 mg dose group (corresponding to an increase from baseline of approximately 52%)
  - · Did not increase in the control group
- · Average high-density lipoprotein (HDL) and triglyceride levels also increased but to a much lesser degree
- · Program-wide data review suggests that lipid elevations are predictable, manageable, and appear to be driven by reductions in albumin
- · Data suggest a favorable trade-off in IgG reductions vs. albumin-LDL changes across doses
- · No relationship to levels of thyroid hormone was observed
- The increases in LDL and reductions in albumin were reversible upon cessation of dosing, and no major adverse cardiovascular events have been reported to date
- Consultations with expert medical advisors have reinforced the company's belief that Immunovant will be able to manage these changes within its development
  program via monitoring and management criteria, adjustments to dosing, and individualized anti-lipid therapy as appropriate



Sources: Immunovant 10-K and 8-K filed June 1, 202

# Data Suggest Favorable Trade-Off in IgG Reductions vs. LDL/Albumin

### 255 mg dose results in modest changes to LDL & albumin, with potent knockdown in IgG

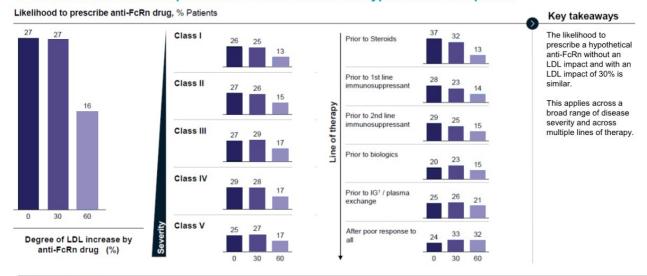


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ote: Data in figure from ASCEND GO-2 trial of IMVT-1401 in Thyroid Eye Disease asked horizontal line represents the lower limit of normal albumin

### **HCP Feedback Consistently Suggests LDL Impact is Manageable**

#### Data below refer to anticipated market share based on hypothetical LDL profile

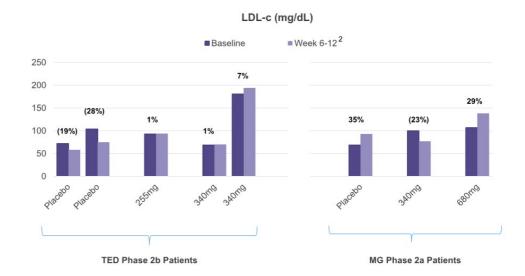


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Immunoglobulin
Source: HCP survey, n=16 (March 2021). Immunovant 8-K filed June 1, 2021

# LDL Was Controlled in Patients who Entered on Statins (a Post-Hoc Analysis)

- Across a variety of doses and different indications, all known patients receiving statins prior to study initiation saw only minimal increases in LDL<sup>1</sup>
- Data suggest that statins can be leveraged to manage lipid levels during treatment with IMVT-1401 when necessary





Data presented based on exploratory analyses performed on stored samples
 Week 6-12 timepoints; each subject shown at the point of maximal duration of blinded treatment period for IMVT-1.

### **IMVT-1401** for Myasthenia Gravis

#### Only subcutaneous anti-FcRn agent with results in Myasthenia Gravis

#### Myasthenia Gravis Overview

- Rare autoimmune disorder affecting an estimated 66,000 people in the US<sup>1</sup>
- Characterized by weakness of muscles including ocular, facial, oropharyngeal, limb, and respiratory muscles<sup>1</sup>
- 15-20% of MG patients will experience at least one myasthenic crisis over their lifetimes, a potentially life-threatening acute complication<sup>2</sup>
- Disease caused by autoantibodies targeting the neuromuscular junction<sup>1</sup>
- ~93% of patients have an identified autoantibody<sup>1</sup>
  - Anti-acetylcholine receptor (AChR) antibodies (~85%)
  - Anti-muscle-specific tyrosine kinase (MuSK) antibodies (~8%)

#### Unmet Need Persists Despite Availability of Treatment Options

- ~10% of MG patients refractory to current treatments, while 80% fail to achieve complete stable remission<sup>3</sup>
- · Existing therapies are associated with significant side effects
  - Early line agents can lead to disease exacerbation and do not always prevent disease progression
  - Treatment for more advanced disease often requires invasive and burdensome infusions
- Patients with anti-MuSK antibodies are more likely to become refractory<sup>4</sup>
  - ~50% of the refractory MG population, despite comprising <10% of the overall MG population
  - Newest treatment option, eculizumab, only indicated for anti-AChR positive patients

Current Treatment Paradigm						
1 <sup>st</sup> Line	2 <sup>nd</sup> Line	3 <sup>rd</sup> Line	4 <sup>th</sup> Line			
<ul><li>Acetylcholinesterase inhibitors</li><li>Corticosteroids</li></ul>	Immunosuppressive agents     Thymectomy	<ul> <li>IVIg</li> <li>Plasma exchange</li> <li>Immunoadsorption</li> <li>Rituximab<sup>3</sup></li> </ul>	• Eculizumab			



1. Meriggioli M.N. and Sanders D.B. Muscle autoantbodies in myasthenia gravis: beyond diagnosis? Expert Review Clinical Immunology, 2012. 2. Sudulagunta S.R., et al. Refractory myasthenia gravis — dinical profile, comorbidities and response to Husimab. German Medical Science. 2015. 3. Ritusimab is not approved by the FDA for myasthenia gravis. 4. Mantegazza R. and Antozzi C. When myasthenia gravis is deemed refractory: clinical signposts and treatment transferance. Thereing defautors in National Planaries. 300 of the State of St

### **IMVT-1401** for Warm Autoimmune Hemolytic Anemia

#### Warm Autoimmune Hemolytic Anemia (WAIHA) Overview

- · Blood disorder marked by red blood cell destruction
- Estimated prevalence of 42,000 patients in the US and 67,000 patients in the EU<sup>1</sup>
- Presentation typically non-specific and occurs over several weeks to months
  - · Fatigue, weakness, skin pallor, shortness of breath
- Severe cases can be fatal<sup>2</sup>

#### **Limited Treatment Options**

- · Currently no FDA-approved therapies for WAIHA
- Only one-third of all patients maintain sustained disease control once steroids are discontinued
  - Majority of patients will require either long-term steroid treatment or additional therapies<sup>3</sup>
- No clear guidelines on choice of treatment in patients failing treatment with corticosteroids
- RBC transfusions are indicated in patients who require immediate stabilization, despite the fact that autoantibodies present in WAIHA patients may react against the transfusion of blood components<sup>1,3</sup>

Current Treatment Paradigm <sup>1,3</sup>						
1 <sup>st</sup> Line	2 <sup>nd</sup> Line	3 <sup>rd</sup> Line	4 <sup>th</sup> Line			
Corticosteroids Red blood cell (RBC) transfusion	Immunosuppressive agents	• Rituximab <sup>4</sup>	Splenectomy			



. Immunovant 10-K filed June 1, 2021. 2. Roumier M., et al. Characteristics and outcome of warm autoimmune hemolytic anemia in adults: new insights based on a single-center experience with 60 patients. American Journal tematology, 2014. 3. Salama A. Treatment Options for Primary Autoimmune Hemolytic Anemia: A Short Comprehensive Review. Transfusion Medicine and Hemotherapy, 2015. 4. Ritusimab is not approved by the FDA for war

## Early Data in WAIHA Trial Demonstrate Promise of IMVT-1401

#### Our outlook on IMVT-1401 efficacy and potential of FcRn class has improved



#### **Previous WAIHA therapy**

1st line - prednisolone

2<sup>nd</sup> line - cyclosporine

 $3^{rd}$  line – prednisolone, azacytidine (ongoing at study start)

	Baseline (Week 1)	Week 3	Week 7	Week 13
Total Bilirubin (mg/dL)	1.6	0.4	0.3	0.3



Note: All data from ASCEND WAIHA, a Phase 2 trial of IMVT-1401 in Warm Autoimmune Hemolytic Anemia.

### **IMVT-1401** for Thyroid Eye Disease

#### Only subcutaneous anti-FcRn therapy in clinical development for Thyroid Eye Disease (TED)

#### **Thyroid Eye Disease Overview**

- TED is also called Graves' ophthalmopathy (GO)
- 15,000-20,000 patients with active TED in the US per year
- Clinical features<sup>1</sup>:
  - Eye bulging ("Proptosis")
  - Eye pain
  - Double vision ("Diplopia")
  - · Light sensitivity
- Can be sight-threatening<sup>2</sup>
- Caused by autoantibodies that activate cell types present in tissues surrounding the eye<sup>2</sup>
- · Close temporal relationship with Graves' disease

#### **Limited Treatment Options**

- Corticosteroids are not effective in all patients and approximately one-third of patients will relapse
- Sight-threatening disease may occur in 3-5% of patients with Graves' disease<sup>3</sup>
  - Medical emergency requiring immediate hospitalization and evaluation for surgery<sup>3</sup>
- Up to 20% of TED patients require surgical intervention<sup>3</sup>

Current Treatment Paradigm						
1 <sup>st</sup> Line	2 <sup>nd</sup> Line	3 <sup>rd</sup> Line	Inactive Disease			
Corticosteroids	Orbital radiotherapy     Immunosuppressive agents	<ul> <li>Rituximab<sup>4</sup></li> <li>Teprotumumab</li> </ul>	Orbital surgery			



1. Davies T, and Burch HB. Clinical features and diagnosis of Graves' orbitopathy (optimismopathy), UpToDate, 2018. 2. Mar./Alicen C. An overview of thyroid eye disease. Eye and Vision, 2014. 3, Bartalena L., et al. Management of Graves Orbitopathy Control and Perspectives. Endocrine Reviews. 2009. 4, Ritification is not perspective. Brother Disease.



### **ASCEND GO-2 Summary**

#### The program-wide review led to unblinding the TED trial and termination of the study

- · We observed declines in total IgG and in Thyroid Stimulating Antibodies throughout treatment
- Approximately 41 subjects reached the 13-week primary endpoint at the time of study termination vs. 77 planned. The study was therefore significantly underpowered to demonstrate efficacy
- We observed changes in proptosis responder rate that were nominally significant in some treatment groups at early time periods with larger patient numbers but were not significant at the 13-week primary endpoint
- We are considering alternative trial designs and patient populations and believe our next trial will be a phase two study.
   We plan to announce the details of this study later this year





#### Developing transformative gene therapies for rare diseases



#### Will Chou, MD CHIEF EXECUTIVE OFFICER

Former Global Commercial Head of Kymriah, Novartis; Head Lymphoma Clinical Development of Kymriah, Novartis



#### Palani Palaniappan, PhD

CHIEF TECHNOLOGY OFFICER

Former Global Technical Operations Head, Sarepta; 25 years of technical operations leadership, multiple gene therapy development programs



#### Punam Malik, MD

KEY SCIENTIFIC ADVISOR

Leading expert in lentiviral gene therapy, stem cell biology and clinical care of hemoglobinopathies; invent of ARU-1801 underlying technologies

#### Aruvant aims to deliver a potential cure for sickle cell disease (SCD) utilizing a lower toxicity conditioning regimen

- ARU-1801 uses a self-inactivating lentiviral vector that contains a proprietary, patent protected γ-globin gene for a novel, highly potent variant of fetal hemoglobin (HbF): HbFG16E
- · ARU-1801's high potency has allowed for engraftment using only reduced intensity conditioning (RIC)
- · Only gene therapy/editing approach to generate potentially curative clinical data without high intensity conditioning (and associated prolonged hospitalizations, extensive neutropenia and loss of fertility)
- · Clinically meaningful reductions in vaso-occlusive events (VOEs) observed in all patients treated to date
- Curative potential with first patient durable response out to at least three years post-treatment
- Composition-of-matter patent expected to provide IP protection until at least 2035
- Aruvant is also developing ARU-2801, a one-time AAV gene therapy for the potential treatment of hypophosphatasia, a potentially devastating, ultra-orphan disorder currently treated with a chronically administered enzyme replacement therapy

	0 N B
	Ongoing New Patient and Follow-Up
	Data Through 2021, Including Data from Five Patients by YE 2021
	Tive Fatients by TE 2021
	IND-enabling studies currently ongoing



# Sickle Cell Disease (SCD) is a Devastating Genetic Disease Caused by Abnormal Sickle Hemoglobin

#### Sickle Cell Disease

- Leads to hemolysis and vaso-occlusive events (VOEs), where sickled red blood cells obstruct circulation, causing severe pain and ischemic tissue injury
- Major complications include chronic hemolytic anemia, stroke, and progressive organ damage
- · Mean age of death in the US is 44 years1

# High unmet need for more patient-friendly potentially curative therapies

- Persistent VOEs with current medical therapy options
- Less than 20% of sickle cell patients have a matched sibling donor<sup>2</sup>
- Complications associated with allogeneic transplant are not well tolerated in adults with SCD

US/EU ROW -17-25M patients<sup>6,7</sup>

-225K SCD patients<sup>3,4</sup>

Eligible for gene therapy<sup>5</sup>

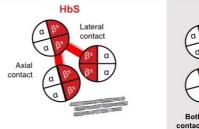
~100K Severe SCD patients<sup>5</sup>

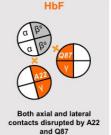
~\$40B Market opportunity5

~25K

#### HbF is the Most Potent Anti-Sickling Globin For Treatment of SCD

HbF disrupts both axial and lateral contacts in HbS polymers8





# Clinical benefit of increasing HbF is extensively described in the literature

- HbF levels > 8.6% are associated with improved survival9
- HbF levels > 20% are associated with a 2-4-fold reduction in hospitalizations<sup>10,11</sup>
- HbF levels > 30% can result in asymptomatic disease<sup>12</sup>



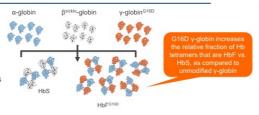
1. Paulukonis S. A. Hagar R. Blood. 2017 Dec; 130(1); 2133. 2. Walters, Mark C. Current opinion in homatology 223, 20(15); 227. 3. US Patient Population: Scide Gold Disease Statistics, CDC. 4. EU Patient Population: European Medicines Agency 5. Based on internal manket research. Material responsibility is based on internal manket research. Material responsibility of the Statistics of the

### ARU-1801's Unique Attributes Drive High Potency that Enables Use of RIC

#### Proprietary G16D Modification Drives Higher HbF Payload Per Vector Copy in Preclinical Studies

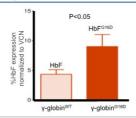
#### G16D mutation in y-globin increases HbF formation

- Changes glycine (G) at position 16 to aspartic acid (D)
- γ-globin<sup>G16D</sup> has demonstrated a higher affinity for α-globin and is thus more likely to form HbF<sup>1-4</sup>



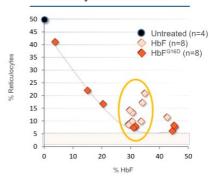
#### Higher G16D potency demonstrated in mouse models

 HbF<sup>G16D</sup> led to 1.5 – 2x more HbF per vector in well-established SCD mouse models<sup>1</sup>



#### HbF<sup>G16D</sup> Payload May Have a More Potent Clinical Anti-Sickling Effect Than Endogenous HbF

#### Hemolysis in SCD mice

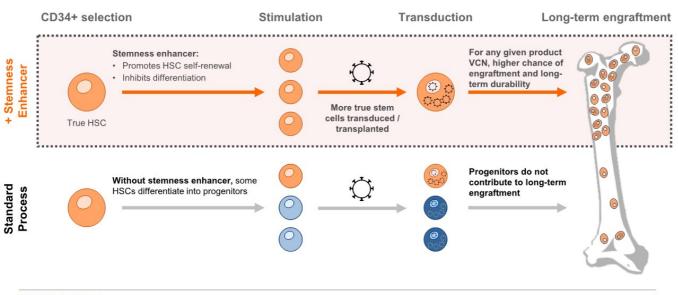


- Lower % reticulocytes indicates less sickling and hemolysis<sup>5</sup>
- At the same level of % HbF (yellow oval)
  - HbF<sup>G16D</sup> is superior to endogenous HbF at reducing reticulocyte count<sup>1</sup>



ARU-1801 IND. 2. Am J Clin Pathol . 1981 Jun;75(6):843-6. 3. Biochimica et Biophysica Acta 1963 Dec; 78(4):637-643 4. J Biol Chem. 2004 Jun 25;279(26):27518-24. 5. J Clin Invest. 2017 Mar 1; 127(3): 750–760

# Our Cellular Manufacturing Process Leverages a Proprietary Stemness Enhancer to Facilitate Engraftment





# ARU-1801 With RIC Has Potential Benefits for Patients, Providers and Payors

Reduced intensity conditioning (RIC) with melphalan 140mg/m² may provide significant clinical benefit compared to the busulfan-based regimen used by the other leading SCD gene therapy candidates, including the potential for lower risk of secondary malignancy

Note: no head-to-head studies of these products have been conducted

	Busulfan 3.2 mg/kg/day <sup>*</sup> (Used by myeloablative gene therapies)	Melphalan 140 mg/m² (Used by ARU-1801)
Neutropenia Recovery Time	20 days¹	7 days²
Platelet Recovery Time	28 days¹	8 days²
Neurotoxicity	Seizure prophylaxis required <sup>3</sup>	No seizure prophylaxis required <sup>4</sup>
Ovarian Failure	70 - 80% <sup>5</sup>	30 - 40% <sup>5</sup>
Chemo Administration	4 days <sup>6</sup> daily PK monitoring	1-hour infusion <sup>4</sup>
Days in Hospital (Median)	44 days <sup>6</sup>	0-5 days <sup>7</sup>
Potential for Outpatient Administration	Low <sup>3</sup> (longer cytopenias, multiple infusions)	High <sup>7</sup> (common in multiple myeloma)
Backup Collection	Required <sup>8</sup>	Not required <sup>9</sup>
Risk if No Engraftment	Rescue transplant required <sup>8</sup>	No rescue required9



Table effects combination of gene therapy protocols, regorited results from gene therapy trials, and literature on the use of three conditioning agents in other settings.

Those adjusted or a propried AUC for businest on 4200 july min. 1 bluested biol 6x50CT 2022. Resolution of Sickle Cell Disease (ECQ) Manifestation of the relation of the Cell Disease (ECQ) Manifestation of the Cell Disease (ECQ) Manif

# bluebird bio MDS/AML Cases Highlight the Importance of Safety for All Gene Therapies

SCD patients at increased risk for malignancy

- Population studies show SCD patients have a 1.5-11x increased risk for hematological malignancies<sup>1,2</sup>
- Concomitant therapies, such as hydroxyurea, are associated with leukemogenesis<sup>3,4,5,6</sup> and we believe may exacerbate risk in SCD

High doses of chemotherapy a known risk

- · LentiGlobin, CTX001 and other gene therapies require high dose myeloablative busulfan
- · ARU-1801 leverages lower dose, reduced intensity melphalan
- Higher doses of alkylating agents lead to higher risk of MDS / AML<sup>7,8,9</sup> and we believe may exacerbate SCD malignant predisposition

Long track record of lentiviral vector safety

- Over 250 patients treated with lentiviral-modified stem cells with no episodes of insertional oncogenesis<sup>10</sup>
- Thousands treated with lentiviral CAR-T11
- Lentiviral vectors originated from HIV-1, which is not associated with tumorigenesis<sup>12</sup>

Lentiviral vector exonerated in BLUE cases

- There are accepted methods to determine if vector was responsible for oncogenesis 13
- bluebird bio conducted systematic analysis of first MDS patient to demonstrate that vector was not responsible; it is
  possible that use of busulfan and underlying disease risk may have played a role<sup>13</sup>
- In addition, bluebird bio has announced that based on available results to date, it is very unlikely that recently reported AML
- case in Phase 1/2 Study was related to lentiviral vector used 14
   Recent MDS case reclassified as not a case of MDS, diagnosis changed by investigator to transfusion-dependent anemia 15

BLUE issues highlight the need for safer conditioning regimens for SCD patients receiving gene therapy



Blueblief bio disclosed 2 recent cases of MDS / AM, no. 21627 via press release. 1. Brusson et al. 18 no. 2017 1977 2. Servinog et al. J. P. Soc Med 2015, 109.303.3. Kladjan J.J. et al. Blood. 2008 Nov. 112(11):1746. 4. Nielsen I. et al. An J. Hematic. 3. Soc Servino (12):3. Servinog et al. J. P. Soc Med 2015, 109.303.3. Kladjan J.J. et al. Blood. 2008 Nov. 112(11):1746. 4. Nielsen I. et al. An J. Hematic. 3. Soc Servino (12):3. Servino (12):

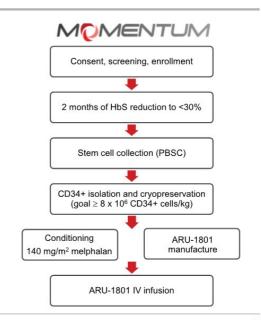
# The MOMENTUM Study is a Phase 1/2 Trial of ARU-1801 Utilizing Reduced Intensity Conditioning (RIC) in Patients with Severe SCD

#### Key Inclusion Criteria

- HbSS / HbSβ0 / HbSβ+ thalassemia
- 18-45 years of age
- Patients with severe SCD (≥2 VOEs per year, or ≥2 lifetime ACS, or requiring chronic transfusions)
- Failed hydroxyurea, actively refused to take it, or have no access
- No matched sibling donor or refused allogeneic transplant

#### Key Exclusion Criteria

- History of stroke or on disease modifying therapy for moderate to high risk for stroke
- Patients with alpha thalassemia (2 or more deletions)

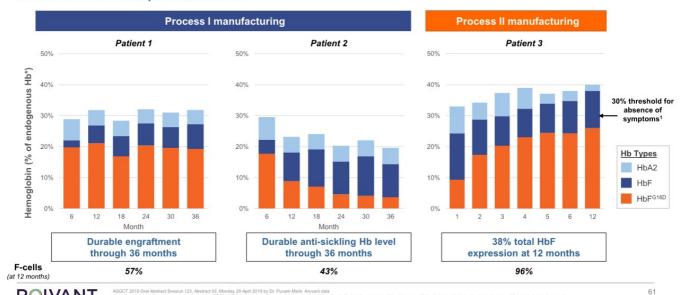




ACS, acute chest syndrome: PBSC, peripheral blood stem cell

# ARU-1801 Has Demonstrated Durable Engraftment Through 36 Months and Potentially Curative HbF Levels Greater than 30% with Refined Manufacturing Process II

#### Data from first three patients to date



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SGCT 2019 Oral Abstract Session 123, Abstract 50, Monday 29 April 2019 by Dr. Punsem Malik. Auvant data
So dendogenous Hb expressed as % of sum (HRP<sup>SHA</sup>, HbF, HbA2, and HbS) to account for transfused HbA blood. Patient 2 expresses ~3% endogenous HbA which is not included in the endogenous Hb calculation as it cannot be stirguished from exogenous HbA during translusions

Ь

# Data Demonstrate Potential to Deliver Durable, Meaningful VOE Reductions to Patients with SCD

		Hospitalized VOEs				Total VOEs	
		Pre-treatment (24 mo)	Post-treatment (24 mo)	Reduction (%)	Pre-treatment (24 mo)	Post-treatment (24 mo)	Reduction (%)
	Patient 1	7	1	86%	41	3	93%
Process I	Patient 2	1	0	100%	20	3	85%
Process II	Patient 3	6	0 at 12 mos	100%	12	0 at 12 mos	100%

- Process I has shown durable engraftment to 36+ months in Patients 1 and 2
- Process II has shown improved product profile with Patient 3 showing highest VCNs, HbF, and F-cells to date
- Additional Process III (Phase 1/2) and Commercial Process (pivotal trial) being developed with the aim of further increasing VCNs



CN, vector copy numb

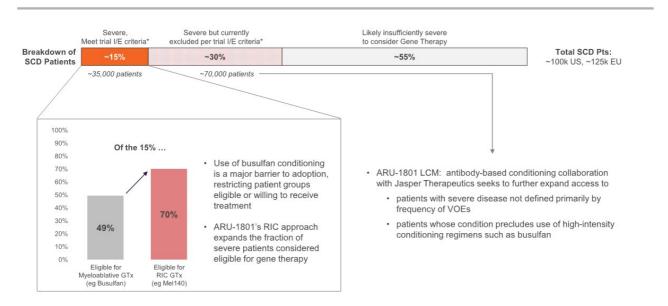
# CMC Process Improvements Scheduled For 2H 2021 to Prepare For Commercial Supply

		1H 2021	2H 2021	1H 2022+		
		Phase 1/2				
	Process I	Process II	Process III	Commercial		
G16D mutation	✓	✓	✓	✓		
Stemness enhancer	✓	✓	<b>✓</b>	1		
Optimized peripheral apheresis		✓	✓	<b>✓</b>		
Optimized MOI		✓	<b>✓</b>	1		
Optimized academic vector purity		✓	✓			
Additional transduction enhancer			✓	✓		
Optimized transduction conditions				<b>✓</b>		
Optimized commercial vector				<b>*</b>		
Centralized commercial cell product manufacturing				<b>4</b>		
Target Average VCN	0.33	~ 1	~1-2	~1-3		
Time of introduction	Ph1/2: Patients 1-2	Ph1/2: Patients 3-4	Ph1/2: Patients 5-9	Pivotal trial		



II. Method of induction: VCN, vector copy number.

## ARU-1801 Key Market Assumptions Based on HCP Research





Limiting trial inclusion/exclusion critoria are similar across SCD gene therapy trials (ag BLUE, CRSP, etc.) and include restriction of genotype (HbSS, HbSgP, HbSgP), threshold frequency of severe VOEs (24 in prior 24 months), and

### ARU-2801 for Hypophosphatasia

ARU-2801 is an adeno-associated virus gene therapy designed to treat hypophosphatasia, a devastating, ultra-orphan disorder that affects multiple organ systems and leads to high mortality

ARU-2801 is a potential one-time gene therapy for hypophosphatasia (HPP) that could replace ERT SOC and deliver durable efficacy without chronic administration



#### **Encouraging preclinical data**

Durable increases in tissue non-specific alkaline phosphatase (ALP) levels through 18 months



#### Potential for curative reduction in disease burden

- · Significant increase in survival
- Amelioration of bone defects with development of mature bone
- · Normalization of body weight and bone density



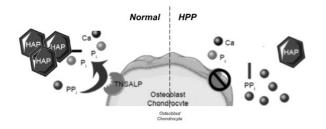
All drugs are investigational and subject to health authority approval.

# Hypophosphatasia (HPP) is a Devastating and Potentially Fatal Orphan Disorder with No Gene Therapy Treatments Available

HPP is caused by mutation in the *ALPL* gene and is characterized by low or no expression of tissue non-specific alkaline phosphatase (TNS-ALP)

#### Mutant TNS-ALP impairs bone mineralization...

- In HPP, TNS-ALP, is mutated and cannot convert pyrophosphate (PPi) to phosphate (Pi), a key component of bone hydroxyapatite
- This results in limited hydroxyapatite formation, and therefore limited bone mineralization



#### ...leading to severe musculoskeletal compromise

- Severe forms result in respiratory failure from chest hypoplasia, seizures, and limb deformity
- Left untreated, 50% of severe perinatal / infantile-onset incident patients die in first year of life¹







All drugs are investigational and subject to health authority approval.

1.3 Pediatr. 2019 Jau 2020 11:51-22 Jau 2020 11

# Chronic Administration, Injection Site Reactions, and Poor Durability of Strensiq Leave High Unmet Need that ARU-2801 Could Potentially Address

Chronic, lifetime injections

- Up to 6x SC injections/week for a lifetime
- Multiple strength products need to be matched with patient weight
- Compliance issues

Short half life with peaks and troughs

- $T_{\text{max}}$  15 20 hours and half-life 2.28 days
- Low bioavailability
- Slow absorption

AEs at injection site

- · Frequent injection site reactions
- Lipohypertrophy shown in 30% of patients, including 70% of juvenile-onset patients

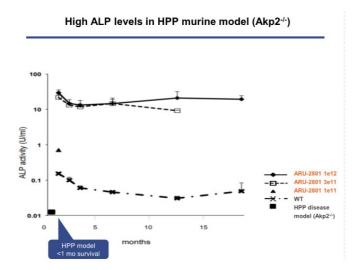
ARU-2801 can potentially eliminate these inherent chronic dosing and PK/PD issues

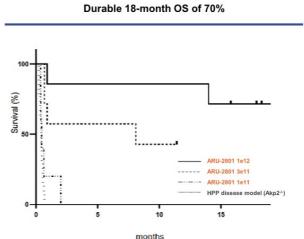


All drugs are investigational and subject to health authority approval.

1. https://www.ema.europa.eu/en/documents/product-information/strensig-epac-product-information\_en.pdf. 2. JCI Insight. 2016 Jun 16; 1(9): e85971. Published online 2016 Jun 16. doi: 10.1172/jci.insight.859

# In HPP Murine Models, ARU-2801 Results in Durable, High Levels of ALP and Survival to 18 Months





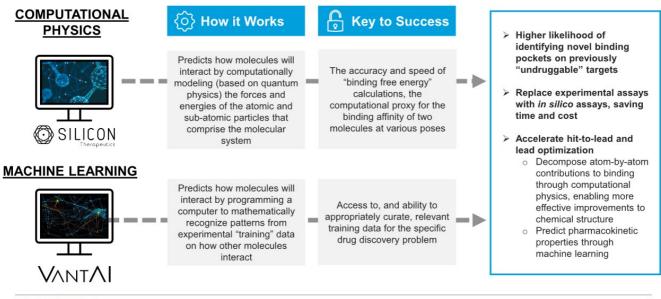
No evidence of ectopic calcifications at these therapeutic doses



If drugs are investigational and subject to health authority approval.

Matsumoto T et alt Molecular Therapy Methods and Clinical Development 2021

# Platform Distinctively Combines Computational Physics and Machine Learning Capabilities

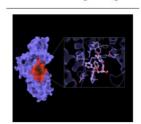


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## V∧NT∕ | Machine Learning & Systems Biology Platform

#### Computational platform powers several core applications

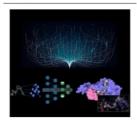
#### De Novo Drug Design



Algorithmically design drugs, reverse engineered from target and disease biology

Ex. VantAl-designed bifunctional degraders and glues exhibited ontarget degradation, including for historically hard-to-drug or undruggable targets

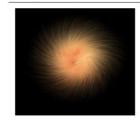
#### **Target & MOA Prediction**



Modality agnostic target prediction. Al-powered novel MOA understanding down to the atomic level

Ex. VantAI evaluated IP repurposing opportunities to identify high priority indications for further development

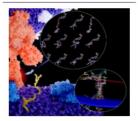
#### **Pathology Interactome Mapping**



Systematic disease and molecular pathway mapping of target profiles

Ex. VantAl accurately predicted offtarget degradation for degrader with no known promiscuity

#### In Silico ADMET



Task-specific models for ADMET properties that leverage the power of embeddings and transfer learning

Ex. VantAl more accurately predicted solubility vs. traditional methods for ~100 bifunctional degraders and glues





## SILICON Computationally Enabled Physics Platform

Force Field Engine
Bespoke parameterization using quantum mechanics on every molecule

#### **Atomic Decomposition**

Visualize atom-by-atom contributions of a ligand binding biologically meaningful timescales identify hit compounds without to a protein

#### **High-Performance Computing**

All-atom simulations at with cluster of >500 GPUs

Virtual Screening
Free energy simulations to ligand training data

#### Research Infrastructure

Rapidly iterate between experiments and computation to drive design cycle



#### Water Thermodynamics

Predict high-energy water hot spots

**Binding Free Energies**Capture all aspects of binding free energy, including flexibility, entropy, and desolvation

Enhanced Sampling
Capture complex biological motions and model proteinprotein interactions

Integrated Biophysics Data Incorporate experimental data to improve simulation accuracy for biologically relevant states



#### **Roivant Biophysics and Structural Biology Advantage**

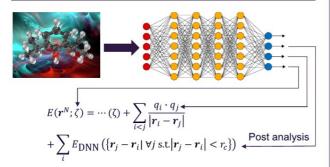
#### **Biophysics Structural Biology Enhance Simulations with** Hydrogen-Deuterium Exchange (HDX) X-ray Crystallography **Biologically Relevant Data** Detect buried protein regions in binary Solved high-resolution crystal and ternary complexes structures for challenging targets Augment simulations to generate KRASG12D atomic-resolution models in days (X-HIF2a ray or CryoEM take months or longer) SMARCA2/VHL Complementary to simulations **Nuclear Magnetic Resonance (NMR) Protein Science** Fragment screening Generated hundreds of protein Binding affinity in solution without protein labels, tags, or attachments samples using 3 expression systems (mammalian, insect, and bacterial) Produced NMR-labeled ADAR1 and Ligand-observed techniques STD & W-LOGSY Protein-detected NMR to characterize interactions with specific pockets



TD: Standard Transfer Difference. W-LOGSY: Water-Ligand Observed via Gradient Spectroscopy

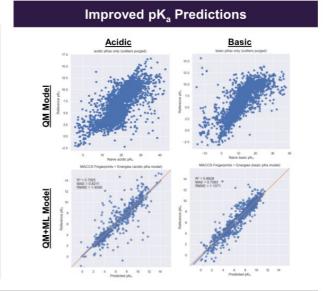
## Improvements from Combining AI and Physics Approaches

#### **QM Force Field with Al Augmentation**



**Physics** — captures key interactions such as hydrogen bonding, electrostatics, dispersion, and bonded terms

Machine Learning — augments the physics-based model by including quantum mechanical data to capture subtle interactions like pi-pi stacking and polarization





## Successfully Solved Crystal Structures for Challenging, High-Value Targets

#### KRASG12D

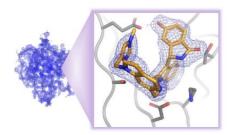
- Number of structures: 2
- · Best resolution: 1.9 Å
- Details
  - G12D mutant
  - · Inhibitors bound to on/off forms
  - Structures within 1 month

#### HIF2a

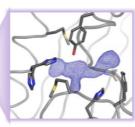
- Number of structures: 3
- · Best resolution: 1.7 Å
- Details
  - Apo/Holo
  - Allosteric
  - · Novel virtual screening hit

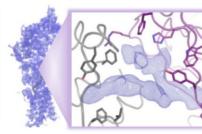
#### SMARCA2/VHL

- · Number of structures: 1
- Best resolution: 2.3 Å
- Details
  - Ternary complex with ACBi1
  - Linker-dependent conformational differences











Apo: unbound. Holo: bound

## Roivant's Platform Unlocks New Opportunities To Drug High Value Targets

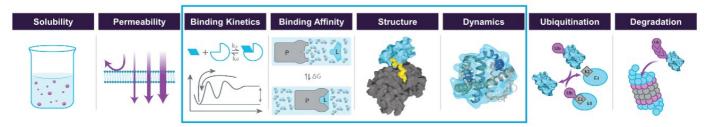
Target Category	Challenge	Opportunity	Roivant Edge
Phosphatases (SHP2, PP2A)	Non-druglike inhibitors due to charged, polar catalytic site	Allosteric inhibitors and/or heterobifunctional degraders/glues	Advanced simulations and integrated biophysics to identify novel, druggable allosteric sites; ML-based protein-protein interface modeling to design optimal degrader pharmacophore
Transcription Factors (AR, STAT3, HIF2A)	Modulation of DNA binding	High-affinity ligands and/or heterobifunctional degraders/glues	Exploration of larger chemical space via free energy simulations and atom-by-atom design tools; use of degron knowledge graph to identify degron motifs and reverse-engineer warhead and recruiter ligands
Signaling Proteins (KRAS, CRAF, JAK2- 617F, STING)	Tuning signal modulation (agonism vs. antagonism)	Designed conformational modulators	Targeted simulations along biologically relevant reaction path
Nucleic Acid Binding Proteins (WRN, ADAR1)	No classic small molecule binding sites	Targeting cryptic pockets and/or heterobifunctional degraders/glues	Long-timescale molecular dynamics, mixed-solvent molecular dynamics, and water thermodynamics to discover novel cryptic pockets



Note: The above are examples of potential applications for our existing platform technologies.

#### **Platform Models Key Steps of Degradation Process**

We utilize an iterative approach that always begins with the fundamental physical process and where our methods can overcome inefficiencies and bottlenecks



## Modeling ternary structure is critical to predictive targeted protein degradation platform

- Computational methods often not suited to accurately predict the ternary complex
- Experimental methods such as X-ray and CryoEM take months



#### Fully Integrated Binding Simulation with Hydrogen-Deuterium Exchange Data

#### **Most Accurate Ternary Structure Prediction Known**

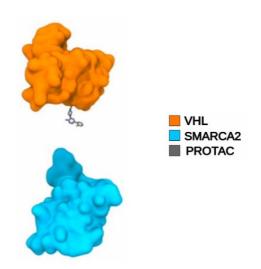
Integration of experimental hydrogen-deuterium exchange (HDX) data offers unique advantage

#### Final Statistics:

- · Warhead-interface RMSD = 0.4 Å
- Ligand-interface RMSD = 0.65 Å
- Fraction of native contacts = 90%

#### Computational Details:

- · Simulation times:
  - 15 µs for formation of encounter complex
  - 5 µs for re-arrangement
- GPUs and time to solution:
  - 32 GPUS x 3 day
- · System size: 125K atoms
- · WE Collective Variables:
  - For d>4.5 Å  $\rightarrow$  CV: Minimum distance
  - For d<4.5 Å  $\rightarrow$  CV: Number of native contacts





# Small Molecule Discovery Pipeline Spans High-Value Targets Across Oncology, Neurology, and Immunology

Target & MoA	Opportunity Profile	Potential Indications/Patient Populations
AR Degrader	Prostate cancer that progresses on AR inhibitors is usually still AR-driven, indicating benefit from degradation     Ability to go after wild type, amplified, and AR mutant variants	Broad prostate cancer (metastatic, non-metastatic, neo-adjuvant settings)¹     Precision medicine AR mutant prostate cancer²
STAT3 Degrader	Historically undruggable transcription factor and central node within JAK-STAT signaling pathway; precision medicine and I/O opportunities	STAT3-mutated-hyperactivated tumors (e.g., PTCL); solid tumors and hematologic malignancies with STAT3-activation in tumor micro-environment (I/O combo potential) <sup>3-4</sup>
BRD4 Degrader	<ul> <li>Specific degrader of BRD4, an epigenetic reader and transcriptional regulator</li> <li>Aim to significantly improve on efficacy vs BETi by fully abrogating BRD4 function</li> </ul>	<ul> <li>Myelofibrosis (treatment-naïve and Jakafi-experienced)<sup>s</sup></li> <li>Other hematologic malignancies<sup>s</sup></li> </ul>
CBP/P300 Degrader	CBP/P300 control expression of oncogenic factors (e.g., AR, c-Myc) in prostate cancer     Synthetic lethality target (LOF mutations) with precision medicine approach	<ul> <li>AR+ prostate cancer (including AR mutants and splice variant subsets)<sup>7</sup>, tumors with CBP or P300 LOF (e.g., DLBCL, FL, NSCLC, bladder cancer)<sup>8</sup></li> </ul>
SHP2 Degrader	Difficult-to-drug protein tyrosine phosphatase and central node downstream of RTKs     Precision medicine and I/O opportunities with mono and combination therapy	Broad potential application across a variety of solid tumors <sup>9-10</sup> Combination opportunities with EGFR inhibitors, KRAS inhibitors, anti-PD1s <sup>11</sup>
SMARCA2/4 Degrader	Synthetic lethality target in multiple tumor types (e.g., SMARCA4 LOF)	SMARCA4-mutated NSCLC (~10% of NSCLC overall) <sup>12</sup> Tumor agonistic indication: SMARCA4-mutated solid tumors <sup>13-16</sup>
KRAS G12D Degrader	Historically undruggable oncogene variant G12D     Most frequently mutated oncogene in human cancers	KRAS G12D mutant tumors <sup>17-18</sup> Highest rates in PDAC, CRC, endometrial, lung cancer <sup>19</sup>



1. Fujila 2019; 2. Brooke 2009; 3. Zou 2020; 4. Shahmarvand 2018; 5. Saenz 2017; 6. Reyes-Garau 2019; 7. Jin 2017; 8. Iyer 2004; 9. Zhang 2015; 10. Chen 2020; 11. Liu 2021; 12. Herpel 2017; 13. Jelinic 2014; 14. Fernando 2020; 15.

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# Small Molecule Discovery Pipeline Spans High-Value Targets Across Oncology, Neurology, and Immunology, continued

Target & MoA	Opportunity Profile	Potential Indications/Patient Populations
mHTT Degrader	Neurodegenerative disease target characterized by CAG repeats and toxic mHTT protein aggregation; no approved therapies can reduce level of toxic mHTT	Huntington's disease <sup>1-2</sup>
STING Degrader	Potential for precision immunology and rare disease medicine approach     Molecularly defined autoinflammatory diseases	STING, type I IFN driven inflammatory diseases: type I IFN-high SLE <sup>3</sup> Neuroinflammatory diseases: subsets of ALS, Parkinson's defined by STING/IF biomarkers <sup>4</sup> Rare monogenic diseases: SAVI and others <sup>5</sup>
NLRP3 Degrader	<ul> <li>Inflammasome; innate immune pathway target; central regulator of IL-1β and IL-18 cytokine secretion</li> <li>Drives inflammation across a broad range of chronic disorders</li> </ul>	<ul> <li>Autoimmune and inflammatory diseases such as Cryoporin-associated periodic syndromes (CAPS), gout, SLE, IBD, Behcet's, and asthma<sup>6-8</sup></li> </ul>
ADAR1 Inhibitor	Intracellular innate immune checkpoint target & biomarker defined tumor cell dependency     Potential to overcome PD1/PDL1 resistance	Type I IFN-high solid tumors including lung, colon, breast, ovarian <sup>9-10</sup>
WRN Inhibitor	Synthetic lethal target required in tumors with DNA damage repair deficiency	MSI colorectal, gastric cancers <sup>11-12</sup> PARP inhibitor combinations <sup>13</sup>
JAK2-617F Inhibitor	Potential for precision medicine approach     Selective for mutants of blood neoplasm driver	<ul> <li>V617F driven myeloproliferative neoplasms: polycythemia vera, essential thrombocythemia, primary myelofibrosis, AML<sup>14-18</sup></li> </ul>
CRAF Inhibitor	Synthetic lethal target required in KRAS and NRAS mutant tumors     CRAF mutant tumors	NRAS mutant melanoma <sup>17</sup> KRASG12X (non G12C) tumors: lung, colon, many other GIs <sup>18-19</sup> CRAF mutant GI cancers: gastric, colon, lung, other <sup>20</sup>
HIF2A Degrader	Synthetic lethal target required specifically in tumors with 'Achilles' heel' mutation	VHL mutant RCC <sup>21</sup> Pheochromocytoma <sup>22-23</sup>



Lakra 2019; 2. Ast 2018; 3. Elkon 2011; 4. Chin 2019; 5. Fremond 2020; 6. Shen 2018; 7. Ll 2020; 8. Wang 2020; 9. Xu 2019; 10. Herbert 2019; 11. Lleb 2019; 12. Zimmer 2020; 13. Chan 2018; 14. Vannucchi 2008; 15. Gollib 2010; 16

ou



## Integrating extensive medicinal chemistry intuition and biology insight with deep, proprietary artificial intelligence capabilities



#### Drew Fromkin

CHIEF EXECUTIVE OFFICER

30+ years leadership in public & private healthcare co's, serves as Vant Portfolio Operating Partner. Previously CEO Tarveda Therapeutics, CEO of Clinical Data (CLDA) (\$1.5 Billion Sale); Head Corp Dev. Merck-Medical.



#### Ruby Holder

CHIEF STRATEGY OFFICER

25+ years in healthcare, the majority spent as a long-short healthcare portfolio manager. Previously VP of Roivant Governance, Managing Partner & Portfolio Manager of Greywall Asset Management



#### Zhihua Sui, PhD

CHIEF SCIENTIFIC OFFICER

30 years of experience in drug discovery and advancement of more than 20 compounds into the clinic across various therapeutic areas. Previously VP Head of Chemistry and Strategic Outsourcing at Agios, also held various le



#### Tiago Girao, CPA

CHIEF FINANCIAL OFFICER

20+ years leading teams in accounting, finance, treasury, investor relations and other corporate operations functions. Previously CFO of Respirant, CFO of Cytori, 10+ years of experience in public accounting at KPMG and Emits 4 Young as Setior Manager



#### lelai Mohammad, PhD

HEAD OF CANCER BIOLOGY

15+ years of experience in oncology research with emphasis on epigenetics. Previously Senior Scientific Director at GlaxoSmithKline



#### Scott Priestley, PhD

HEAD OF DISCOVERY CHEMISTRY

234 years leading drug hunting, chemistry teams where he delivered numerous development compounds across various disease areas. Previously Director of Discovery Chemistry at Bristol Myers



- Proteovant's protein degradation platform is supported by an initial \$200 million equity investment by SK Holdings, a strategic investment arm of SK Group in Korea
- Broad, initial degrader pipeline obtained through the acquisition of Oncopia Therapeutics, which was cofounded by Dr. Shaomeng Wang at the University of Michigan. Long-term discovery partnership established with Dr. Wang.



Dr. Wang is a world-renowned scientist focused on the discovery of protein degradation, at the University of Michigan. Over 15 years, Dr. Wang and his team have developed a pipeline of degraders for more than 10 targets and has an IP estate of hundreds of patents in the US and about

- Leveraging Roivant's investments in computational sciences through close collaborations with VantAI (machine learning and systems biology) and Silicon Therapeutics (computational physics)
- · Assembled a world-class team
- · Robust degrader patent estate



Il drugs are investigational and subject to health authority approv

# Proteovant's Degrader Discovery Approach Mirrors Roivant's Drug Discovery Philosophy



## Target

"Investment lens" for target identification, powered by computational tools and interdisciplinary team of the property to the solid and data scientists



#### Degrader Expertise

Novel ligands, multi-year partnership with premier academic lab and modality-specific medicinal chemistry expertise



#### **VantAl**

Leading machine learning-based in silico platform for design and optimization of protein degraders, continuously fed by experimental results from across



#### **SiliconTx**

Leading computational physics platform for in silico design and optimization of small molecule therapeutics, integrated with proprietary supercomputing cluster



#### **Wet Labs**

In-house facility fully equipped for biophysics, synthetic chemistry, crystallography and biology; tightly integrated with in silico capabilities to augment simulations and generate high resolution crystal structures



#### **Development**

Track record of success in clinical trial execution; ability to design, initiate and complete trials rapidly

#### Small Molecule Discovery Engine

#### Leader in Computational Drug Discovery

Unique combination of computational physics and machine learning based platforms for *in silico* design of small molecules



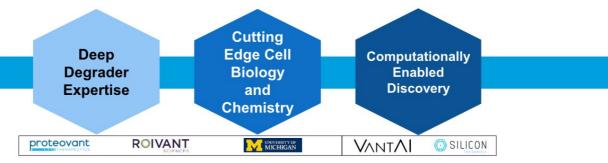
#### Leader in Degrader Discovery

Initial pipeline of degraders for targets spanning oncology, immunology, and neurology, with first Phase 1 initiation expected in 2022



#### **Proteovant Will Lead, Not Follow**

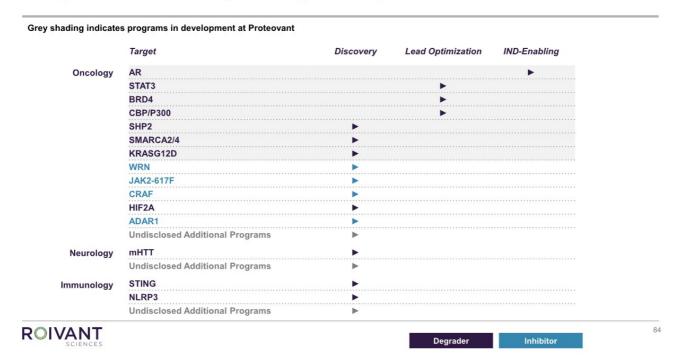
Proteovant is committed to becoming the leader in the discovery and development of novel protein degraders by integrating...



...to deliver treatments to patients with debilitating diseases where unmet medical need continues to exist



## **Computational Discovery and Degrader Pipeline**



#### Novel AR Degrader Expected to Initiate Phase 1 in 2022

Orally-administered androgen receptor (AR) degrader with excellent drug-like properties, broad mutant coverage and potential to move upstream in prostate cancer treatment paradigm

#### **Unmet Need in Prostate Cancer**

- With ~200k new cases annually in the US, prostate cancer represents a significant market opportunity for which AR is a clinically validated target
- Fully shutting down the AR pathway via AR degradation (vs inhibition) has
  potential to improve upon response rates and durability achieved with existing
  AR antagonists -- both in refractory and earlier-line prostate cancer patients<sup>2</sup>
- · Expected to initiate Phase 1 in 2022

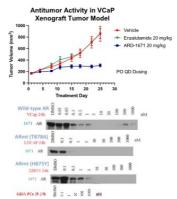
#### Robust Preclinical Data Package with Clear Path to Clinic

- Multiple highly potent and selective oral AR degraders with distinct chemistries and excellent drug like properties
- · Lead candidate degrades both wild-type and other AR mutants
- · Strong activity observed in models in which enzalutamide is inactive
- Encouraging safety and tolerability profile in non-GLP toxicology studies completed to date
- Planned development path includes both refractory and early-line settings (e.g. mCRPC, nmCRPC), including combination therapy
- · IND-enabling studies ongoing

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National Cancer Institute SEER Cancer STAT Facts: 2. Aggarwal 2018

Lead Candidate (ARD-1671) Demonstrates Inhibition of Tumor Growth in a VCaP Xenograft Model Compared to Enzalutamide (Xtandi) and has Broad Activity *In Vitro* Across Wild Type and AR Mutants



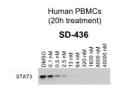
- ARD-1671 (lead candidate) achieved 64% tumor growth inhibition on treatment day 25 in an intact VCaP xenograft tumor model, whereas enzalutamide achieved -1%
- Dramatic prostate weight reduction in dogs in 21day DRF study starting at 1 mg/kg, consistent with expected pharmacodynamic effect
- ARD-1671 potently degrades AR in VCaP (AR wt), LNCaP (T878A), MDA-Pca-2b (L702H and T878A) cellbased models

# Highly Potent STAT3 Degrader Has Potential Applications in STAT3-Driven Hematologic Malignancies and Immuno-Oncology

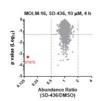
#### **STAT3 Overview**

- STAT3, a transcription factor, has been implicated as a direct driver of multiple tumor types and contributes to an immune-suppressive tumor microenvironment (TME), suggesting an important role in immuno-oncology<sup>1-3</sup>
- Historically "undruggable," despite over 20 years of industry effort, largely due to specificity and potency challenges
- · Highly potent and selective STAT3 degraders in lead optimization
- Intend to develop in select cancers with intrinsic hyper-activated STAT3 signaling and in tumors where STAT3 degradation can unlock anti-tumor immunity

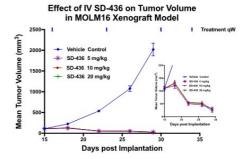
## Potential STAT3 Degrader Lead Potently and Selectively Degrades Wild Type and Mutated STAT3 Proteins in Cells







STAT3 Degrader Achieves Deep Responses in Xenograft Tumor Model (Leukemia) with Activated STAT3 Pathway



STAT3 degrader at 5 mg/kg weekly achieved rapid and complete tumor regression



1. Beebe 2018; 2. Yu 2009; 3. Lee 2019

#### **Proteovant Summary**

- · Broad pipeline of targeted protein degraders initially to over 10 targets
- Well financed to advance key programs to the next level of value creation and lead degraders into clinical trials
- World-class Proteovant team established to discover and develop targeted protein degraders and execute on the business plan
- Long-term, expansive relationship with Shaomeng Wang of University of Michigan and founder of Oncopia Therapeutics
- Unique access to proprietary, industry-leading machine learning and computational physics capabilities and resources within Roivant to rapidly create novel, well-designed degraders
- Anticipate steady stream of degraders to begin to enter clinical development in 2022 and beyond



ppendix			_

## **Key Near-Term Potential Catalysts**

	Tapinarof NDA Filing in Psoriasis	Mid-2021 🗸
dermavant⁻	FDA Approval Decision on Tapinarof for Psoriasis	Mid-2022
	Tapinarof Phase 3 Initiation in Atopic Dermatitis	
	IMVT-1401 Phase 3 Initiation in Myasthenia Gravis	Late 2021 or Early 2022
MMUNOVANT	IMVT-1401 Phase 2a Restart in Warm Autoimmune Hemolytic Anemia	Late 2021 or Early 2022
	Two New Indications for IMVT-1401 Expected to be Announced	1H 2022
	First Patient Dosed with ARU-1801 Manufacturing Process III	2H 2021
ARUVANT	Clinical Data from Additional ARU-1801 Phase 1/2 Patients	2H 2021
	ARU-1801 Phase 3 Initiation	2H 2022
kinevant	Namilumab Phase 2 Initiation in Sarcoidosis	1H 2022
() lysovant	LSVT-1701 MAD Initiation	1H 2022
	In-License Multiple Potentially Category-Leading Drugs	Ongoing
ROIVANT	Phase 1 Initiation for First Degrader Candidate	2022
	Multiple Additional Degrader Candidates Entering IND-Enabling Studies Each Year	Starting 2022

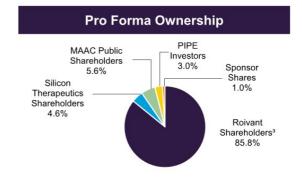
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Il catalvst timinos are based on current expectations but may be subject to change. All trademarks are property of their respective owners.

#### **Transaction Overview**

Transaction Overview (\$M, except share data)		
Pro forma shares outstanding (M) <sup>1</sup>	734.2	
(x) Illustrative share price	\$10	
Common equity value	\$7,342	
(-) Pro forma net cash <sup>2</sup>	(2,342)	
Firm value	\$5,000	

Sources (\$M)			
Sources SPAC cash in trust	\$411		
PIPE	220		
Total sources			



Uses (\$M)	
Uses	
Cash to balance sheet	\$576
Expenses <sup>4</sup>	55
Total uses	\$631



Source. Company filings and estimates. All figures are as of Discriber 31, 2020 unless otherwise noted.

1. Assumes no that redemptions and excludes impact of warmstand an 20% and 10% sponsor have earn—outs if stock price closes at or above \$15 and \$20, respectively, for 20 out of 30 trading days within 5 years of closing, includes shares issued and expected to be issued to former Silicon Timerpautics shareholders, included assumed settlement of the \$1000M "Second Trancho" in equity, schools because part of copies and the state of t

#### **Roivant's Vant and Cash Holdings**

#### All figures as of Dec. 31, 2020 except where otherwise noted

Cash Position<sup>1</sup>

\$2,153M Consolidated \$1,694M Centrally Funded<sup>2</sup>

Total Debt

Pro Forma Cash Runway

Private Vant Ownership				
Vant	% Basic	% Diluted		
Dermavant	100%	86%		
Aruvant <sup>5</sup>	88%	80%		
Proteovant <sup>6</sup>	60%	60%		
Genevant <sup>7</sup>	83%	69%		
Lysovant	100%	99%		
Kinevant (Namilumab)8	88%	88%		
Kinevant (Gimsilumab)	100%	99%		
Affivant <sup>9</sup>	100%	100%		
Cytovant <sup>10</sup>	72%	68%		
Datavant <sup>11</sup>	52%	48%		
VantAl	100%	100%		
Lokavant	90%	86%		
Alyvant	97%	94%		

Public Vant Ownership <sup>12</sup>				
Vant	# Shares	% Basic	% Diluted	
Immunovant	56.4M	58%	54%	
Arbutus	38.8M	35%	32%	
Sio Gene Therapies	18.6M	33%	29%	

- Includes cash, cash equivalents, and restricted cash. Excludes \$200 million investment from SK Holdings Co., Ltd. into Proteovant (half funded in January 2021 and the balance is committed to be funded in July 2021), includes \$75 million restricted cash in secrew for the DSP transaction, which is expected to be released to Rhivant in June 2021. Datawart, Arbutus and Sio Gene Threspies are not consolidated.
  Consolidated debt balance of \$166. Sin allion is all Dermand Sciences Ltd. (non-resourse to Roivant). Dermand and NovaQuest entered into a funding agreement jurisuant to which Dermand both and secretary and secretary and secretary and secretary agreement pursuant to which Dermand both and secretary and secretary agreement of regulatory and sels an relisionse or events of termination. Dermand into certain variable future payments actualized as a self-indice of the secretary and sels an relisionse or events of termination. Dermand into certain variable future payments actualized the self-indice of the self



## **Net Cash Detail**

## All figures as of Dec. 31, 2020 except where otherwise noted

Key Cash and Debt Items (\$M)		Notes
Roivant consolidated cash	\$2,153	Includes cash, cash equivalents, and restricted cash
(+) Expected net proceeds from MAAC business combination and PIPE	576	Assumes no redemptions and \$55M expenses <sup>1</sup>
(-) Estimated SiTX cash payment	(15)	Subject to additional adjustments
Pro forma cash balance	\$2,715	
(-) Roivant consolidated debt	(166)	Primarily reflects \$146M related to fair value measurement of Dermavant-NovaQuest funding agreement
(-) Non-controlling interest	(207)	Reflects the aggregate amount attributable to non-controlling equityholders, primarily related to share of subsidiary cash attributable to them
Pro forma net cash	\$2,342	



Source: Company filings and estimates. Amounts may not add up due to rounding.

## Potential Milestone and Royalty Obligations for Selected Assets

Asset	Partner(s)	Geography	Remaining Contingent Milestones and Royalties
Tapinarof (Dermavant)	GlaxoSmithKline, Welichem Biotech	Worldwide, excluding China and Japan <sup>1</sup>	£100M upon marketing approval of tapinarof in the US to GlaxoSmithKline     Up to CAD\$150M upon the achievement of certain development and commercial milestones to Welichem <sup>2</sup>
IMVT-1401 (Immunovant)	HanAll Biopharma	North America, European Union, United Kingdom, Switzerland, Latin America, Middle East, and North Africa	Up to an aggregate of \$442.5M upon the achievement of certain development, regulatory and sales milestones     Tiered royalties from mid-single digits to mid-teens on net sales
ARU-1801 (Aruvant)	Cincinnati Children's Hospital	Worldwide	Up to \$30M upon the achievement of certain development, regulatory, and sales milestones     Low to mid single-digit royalties on net sales
LNP and Ligand conjugate delivery technologies (Genevant)	Arbutus	Worldwide	<ul> <li>Tiered low single-digit royalties on net sales by Genevant</li> <li>If Genevant sublicenses IP licensed from Arbutus, Genevant to pay Arbutus the lesser of: (i) up to 20% of royalty-related receipts received by Genevant from such sublicensees and (ii) tiered low single-digit royalties on net sales by sublicensees.</li> </ul>
Targeted Protein Degradation Platform (Oncopia Therapeutics)	University of Michigan	Worldwide	Up to \$659M upon the achievement of certain milestones to prior Oncopia shareholders     Up to \$8.6M upon the achievement of certain development and commercial milestones to University of Michigan for the first product for each molecular target covered by intellectual property included in the agreement     Low-to-mid single-digit royalties on net sales to University of Michigan
Namilumab (Izana Bioscience Limited)	Takeda Pharmaceuticals	Worldwide	Up to \$37M upon the achievement of certain milestones to prior Izana shareholders     Tiered royalities ranging from low-single digits to the sub-teen double digits to prior Izana shareholders     Up to \$3.8M upon the achievement of certain milestones to Takeda     High single-digit royalties on net sales to Takeda
LSVT-1701 (Lysovant)	iNtRON Biotechnology, Inc.	Worldwide	<ul> <li>Up to \$42.5M upon the achievement of certain development and regulatory milestones (with respect to the originally licensed endolysin), and up to a maximum of \$37.5M in development and regulatory milestone payments (with respect to each of any new endolysins), and up to \$940M in commercial milestones</li> <li>Low-to-mid-teens royalties on net sales</li> </ul>



1. Dermavant also entered into a collaboration and license agreement with Japan Tobacco Inc. (JT) for exclusive rights to develop, register and market Tapinarof in Japan. Dermavant is entitled to up to \$53M upon the achievement of certain milestones and royalties on sales.

#### **Datavant Merger Overview**

#### **Key Transaction Terms**

#### Structure

- Datavant to merge with Ciox Health, with the combined entity to be named Datavant
- The implied enterprise value of the combined company at the conversion price cap of the new preferred equity investment being made concurrently with closing will be ~\$7BN. This enterprise value implies an equity value of ~\$6.1BN, after netting out ~\$900M of debt and other adjustments
- Former Datavant shareholders to receive a mix of cash and equity in the combined entity upon closing
  - o Former Datavant shareholders will receive ~\$550M in cash, of which Roivant will receive ~\$317M in cash
  - Assuming a ~\$7BN enterprise value, former Datavant shareholders will own ~24% of the combined entity on a fully diluted basis, including a ~12% interest to be held by Roivant (without giving effect to certain liquidation preferences to be held at closing by the new preferred equity shareholders)
- · Merger is subject to customary closing conditions, including the consummation of Ciox Health's equity financing and regulatory approvals

Timeline

Terms

· Expected to close in 3Q 2021



## **Dermavant Financing Overview**

#### **Key Transaction Terms** • \$160M revenue interest purchase and sale agreement with three institutional investors, and concurrent \$40M senior secured credit facility with one of the institutional investors Structure Proceeds from the \$40M credit facility have been used to repay all amounts outstanding under the loan and security agreement with Hercules, with the remainder of net proceeds used for working capital and general corporate purposes Dermavant to receive \$160M committed funding, subject to approval of tapinarof by the FDA Revenue Interest **Purchase and Sale** Dermavant to pay to investors a capped single-digit revenue interest in net sales of tapinarof for all dermatological indications in the United States Agreement Terms Closed in May 2021, with funding of the revenue interest financing to occur following the approval of tapinarof by the FDA (expected mid-2022) · Dermavant received the proceeds from a \$40M senior secured credit facility with one of the institutional investors · Five-year maturity and an interest rate of 10% per annum Credit Facility Terms Dermavant issued to the institutional investor a warrant to purchase 1,199,072 common shares at an exercise price of \$0.01 per common share · Closed and funded in May 2021



## **Sumitomo Options Termination Overview**

# Sumitomo terminated all of its outstanding options to acquire Roivant's ownership interest in Vants Sinovant transferred its Greater China rights to lefamulin, vibegron, rodatristat ethyl and RVT-802 to Sumitomo and its affiliates¹ In connection with the termination of Sumitomo's option to acquire Roivant's ownership interest in Genevant, Sumitomo entered into an agreement to pursue certain future collaborations with Genevant Roivant to receive a \$5.0M payment from Sumitomo Timeline Closed in June 2021



1. For Infamulin, transferred rights cover Greater China (Mainland China, Taiwan, HK, Macau); for vibegron, transferred rights cover Mainland China, for each of RVT-802 and rodatristat ethyl, transferred rights cover Greater China and

#### **Silicon Therapeutics Transaction Overview**

## **Key Transaction Terms** Structure

**Upfront Consideration** 

- Acquisition (via mergers) of 100% of the Silicon Therapeutics (SiTX) business other than certain rights and obligations related to its STING Agonist Phase 1
  candidate
- · Aggregate consideration, payable to SiTX equity holders as follows:
  - Approximately 23.7M shares of Roivant common stock plus approximately \$14.5M cash (subject to certain transaction adjustments and holdbacks, and
    pro forma for the Montes Archimedes business combination), payable at closing of the acquisition (the "First Tranche")<sup>1</sup>; and
  - o \$100M payable at the earlier of (a) approximately 30 days following the public listing of Roivant's common stock or (b) 12 months after the closing of the acquisition (the "Second Tranche")
    - o In the case of (a), payable, at Roivant's election, in cash or in Roivant common stock at price per share based on a VWAP calculation
      o In the case of (b), payable in cash
- Shares issued in the First Tranche will become subject to customary lockup at SPAC closing
- The Second Tranche, if issued in Roivant common stock, will be subject to same lockup terms as PIPE investors and eligible to be registered on any PIPE related resale registration statement

#### Milestones

• Contingent cash milestones tied to regulatory approval and commercialization of three discovery stage products: (i) WRN Antagonist, (ii) ADAR1 antagonist, and (iii) JAK2 v617f Selective Antagonist

#### Timeline

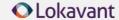
Closed in March 2021



## Growing Technology Capabilities in Discovery, Development, and Commercialization Power Successful Outcomes Across Roivant and Vants

#### DRUGOME1

- DrugOme is a computational ecosystem that enables fast, highquality, and customized analyses to inform decision-making across the entire drug development continuum
- DrugOme integrates three key data types:
  - Natural language processing used on text, literature, and documents
  - Drug development data on molecules, targets, and trial data
  - Real-world data and evidence from patients, physicians, and payers



- Lokavant offers software that integrates real-time data from ongoing clinical trials and monitors risks related to time, cost, and quality
- Proprietary data model serves as a "common language" for trial operational data and enables realtime data integration
- Al trained on proprietary dataset of 1,300+ trials designed to identify the most important risks quickly, when there is still time to mitigate them
- Deployed as Parexel's next generation remote monitoring platform

## **O**DATAVANT

- Datavant seeks to power every exchange of health data, unlocking a massive ecosystem of companies using linked, longitudinal data to improve patient outcomes
- Continued growth across health data network, including >400 organizations and >100 subscription customers
- Powers the advanced use of realworld evidence, patient finding, outcomes research, and commercial analytics
- Customers and partners include Janssen/J&J and other top 20 pharmas, ZS, Medidata, Cigna, Parexel, Symphony Health, Komodo Health, and the NIH
- Datavant and Ciox Health to merge, creating the nation's largest health data ecosystem in a \$7B enterprise value transaction



- Alyvant is a proprietary pharma commercialization technology for physician and patient segmentation, targeting, and engagement
- Generates dynamic call plans uniquely prioritized based on likelihood to prescribe by integrating patient and payor data with physician behavioral characteristics
- Salesforce app drives adherence to call plans and reprioritizes physician outreach based on feedback from the field
- During an initial co-promotion of three specialty products, Alyvant demonstrated a 223% year-over year increase in the total number of prescriptions written by the physicians covered and an estimated 50% improvement in the efficiency of activating new prescribers



Rolvant retains a license to DrugOme, which is owned by DSP and managed by Sumitovan

#### **Genevant Overview**





Pete Lutwyche, PhD

CHIEF EXECUTIVE OFFICER
Former Chief Technology
Officer at Arbutus Biopharma;
Head of Pharmaceutical
Development at QLT; 20+ years
experience in development of
LNP products



PRESIDENT AND CHIEF LEGAL OFFICER

Pete Zorn

Former Chief Corporate Officer and General Counsel at Albireo Pharma; General Counsel and VP, Communications, Santaris Pharma; General Counsel and SVP, Targacept



James Heyes, PhD

CHIEF SCIENTIFIC OFFICER

Former VP, Drug Delivery at Arbutus Biopharma; over 17 years experience in lipid chemistry and nucleic acid drug delivery; over 20 issued and published US patents in lipid nanoparticle and ligand contients to exhoultent conjugate technology

#### **Industry-Leading Nucleic Acid Delivery Company**

- World-class delivery platforms to enable delivery of mRNA, siRNA, gene editing constructs, and other nucleic acids
- Best-in-class proprietary lipid nanoparticle (LNP) platform and proprietary ligand conjugate platform
- · Focused business of collaboration around delivery expertise and technology platforms
- · Offers partners attractive potential to deliver payloads to traditionally hard-to-reach tissues and cell types, as well as nucleic acid design capabilities
- More than 600 LNP-related issued patents and pending patent applications, directed to individual lipid structure, particle composition, particle morphology, manufacturing and mRNA-LNP formulations

#### **Business Model Designed to be Profitable While Building** Further Advances in Nucleic Acid Delivery Technology

- · Genevant uses its expertise in the delivery of nucleic acid therapeutics to develop optimal delivery systems for its collaborators' identified payloads or target tissues
- · Genevant provides collaborators access to validated technology to deliver nucleic acid therapeutics, eliminating the need to build internal delivery expertise or build IP estate from scratch in complex field
- · Genevant typically retains ownership or certain rights to delivery-related IP developed in context of collaboration, which can be leveraged for other out-licenses and to build on developments for future deals

Business model exemplified by numerous recent collaborations and licensing deals, including for I Gritstone's COVID-19 vaccine, Sarepta's gene editing therapeutics for specified neuromuscular diseases, and Takeda's nucleic acid therapeutics directed to historically inaccessible hepatic stellate cells to treat liver fibrosis, all of which use Genevant's LNP delivery technology



#### **Genevant Has Two World-Class Delivery Platforms**



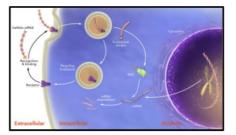
#### Lipid Nanoparticle (LNP)

- · Proven, best-in-class technology
- LNP technology used in FDA-approved RNA Tx (Alnylam's Onpattro)
- Clinically validated for hepatocyte and vaccine use; developing for other tissues and cell types, including lung, eye, stellate and immune cells
- Validated further by collaborations and licenses granted to Alnylam, BioNTech, Takeda, Sarepta, Gritstone and others
- · 600+ issued patents and pending patent applications



#### **Ligand Conjugate**

- Novel GalNAc ligands deliver to liver
- Equal or better preclinical potency and safety compared to current industry benchmark
- Applying delivery expertise to design of novel extrahepatic ligands to expand therapeutic reach
- Developing next-generation ligand conjugate platform for bestin-class GalNAc and enhanced extrahepatic utility







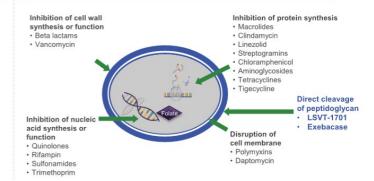
## Novel endolysin for the potential treatment of *Staph aureus* bacteremia that may address serious unmet medical need in the treatment of serious bacterial infections

## Potential Treatment of *Staph aureus* Bacteremia (SAB) and Infective Endocarditis (IE)

- LSVT-1701 is a novel bacteriophage-derived biologic candidate with potent, selective, and rapid bactericidal antistaphylococcal activity including multi-resistant strains via cell wall hydrolysis
- Preclinical data suggest ability to dissolve bacterial vegetations

   in preclinical not head-to-head trials in rabbit IE model, LSVT-1701 achieved complete experimental sterilization on top of daptomycin, whereas daptomycin antibiotic regimen alone and ContraFect's exebacase on top of daptomycin did not<sup>1</sup>
- Based on preclinical toxicology and safety data to date, LSVT-1701 has the potential to be given at multiple and higher doses than exphanase
- We anticipate initiating a Multiple Ascending Dose study in patients with complicated SAB including IE in the first half of 2022

#### Novel Endolysin Mechanism of Action Compared to the Standard of Care Antibiotics





All drugs are investigational and subject to health authority approval.

1. Huang DS, Gasket E, Kerzee N, Borroto-Esoda K, Lowy S, Xiong YO, Abdelhady W, Bayer AS. Efficacy of Anti-Staphylococcal Lysin, LSVT-1701, in Combination with Deptomycin in Experimental Left-Sided Infective Endocardids due
with Michieffice-Resident Sabenholococca waven (MRSA). Antimited Aparts Chemistry And COSSISSIO del: 10.1128/AAC 00508-21.



#### Clinically validated as a novel class of bacteria treatment

#### **High Unmet Need**

- There are an estimated 226,000 patients with SAB and 50,000 with IE each year in the US1
- ~32% of SAB is complicated due to sepsis, comorbidities, or dialysis, and ~28% of SAB is refractory1
- · Staph aureus bacteremia can result in high 30-day mortality of ~20% despite standard of care antibiotics2
- Every year, SAB patients account for ~\$7.4BN in direct hospital cost in the US alone. Sepsis due to SAB is a major cost driver3
- LSVT-1701 has the potential to achieve best-in-class positioning on top of standard of care for hard-to-treat infections





#### **Strong Value Proposition**



#### LSVT-1701 has the potential for:

- Rapid antibacterial activity: Potential rapid and highly effective lytic action
- Species specificity: Anti-staphylococcal endolysins provide pathogen-targeted bacteriolysis and preserve normal flora
- Low propensity for resistance: Target binding sites are highly conserved and essential to bacteria viability
- Synergy with standard of care: Potential to be used to treat antibiotic-resistant bacteria and administered concurrently with antibiotics
- Effective against biofilms: Eradicated and cleared biofilm in animal models where standard of care is ineffective
- Effective against all strains: In vitro susceptibility data demonstrates activity profile for both MRSA/MSSA, and multi-resistant clinical isolates



All drugs are investigational and subject to health authority approva

#### **Significant Clinical Potential**



LSVT-1701 has the potential to be the best-in-class treatment on top of standard of care for populations with high medical needs, such as those with complicated MRSA and MSSA bacteremia and left-sided infective endocarditis

In Vitro Data

- Narrow and well-defined LSVT-1701 MIC range (MIC<sub>90</sub> 2 ug/ml) across a diverse collection of current clinical S. aureus isolates including MRSA, MSSA, vancomycin-intermediate S. aureus (VISA), and glycopeptide-intermediate S. aureus (GISA)<sup>1</sup>
- Comparable MIC range for 82 CoNS isolates (coagulase-negative staphylococci)
- LSVT-1701 not adversely affected by decreased susceptibility or resistance to various antibiotics, further confirming bactericidal activity

In Vivo Data

- · LSVT-1701 multi-dose regimen has demonstrated complete sterilization of tissues in a rabbit infectious endocarditis model
- Demonstrated in vivo postantibiotic effect (PAE) of ≥48 hours in non-neutropenic murine bacteremia (MSSA sepsis) model
- · No dose-limiting toxicities such as vascular lesions or immunogenicity observed following administration of multiple doses

Clinical Data

- In a clinical study evaluating single and multiple ascending IV doses in 51 healthy subjects, no serious adverse events were reported
- Observed mild to moderate adverse events (AEs) included chills/rigors, infusion site reactions, pyrexia, headache, myalgia, and fatigue



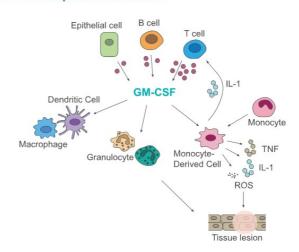
All drugs are investigational and subject to health authority approval.

I, husing DB, Sader HS, Rhomberg PR, Gaustel E, Borroto-Esoda, K. Anti-staphylococcal lysin, LSVT-1701, activity. In vitro susceptibility of Staphylococcus aureus and coagulase-negative staphylococci (CoNS) clinical isolates from around the world collected from 2002 to 2019. Submitted to DMID.



#### Mid-stage program with a potentially fast path to market in an orphan indication

- Roivant is developing a fully human anti-GM-CSF monoclonal antibody, namilumab, with broad potential in autoimmune diseases
- GM-CSF is a key pathogenic cytokine that acts as a proinflammatory signal, prompting macrophages and other activated immune cells to launch an immune cascade that ultimately results in tissue damage<sup>1</sup>
- In multiple Phase 2 studies, anti-GM-CSFs have been welltolerated and have demonstrated the potential to improve symptoms in autoimmune diseases including rheumatoid arthritis and giant cell arteritis<sup>2,3</sup>
- Namilumab has the least frequent subcutaneous dosing in the anti-GM-CSF class (Q4W) and has been studied in ~300 patients to date
- Multiple data points converge on GM-CSF as a target for pulmonary sarcoidosis, namilumab's lead indication
- We plan to initiate a Phase 2 trial in sarcoidosis in the first half of 2022 and to explore additional applications of namilumab in other autoimmune diseases





All drugs are investigational and subject to health authority approval.

1. Becher 2016; 2. Kiniksa Announces Positive Data from Phase 2 Trial of Mavrillimumab in Giant Cell Arteritis, October 2020; 3. GSK Presents New Efficacy and Safety Data of an Anti GM-CSF Antibody in Patients with Rheumatoic

# Namilumab has First-in-Class Potential for Pulmonary Sarcoidosis and Attractive Dosing Profile Across Mid-to-Late Stage Anti-GM-CSFs

Multiple avenues for expansion across validated indications + white space indications

Drug	Company	Dosing	Route	Stage and Major Indications Being Pursued
Namilumab	kınevant	Q4W	sc	Preparing Phase 2 in pulmonary sarcoidosis
Otilimab	gsk	QW	SC	Currently running Phase 3 in rheumatoid arthritis
Mavrilimumab (GM-CSFR)	KINIKSA PHARMACEUTICALS	Q2W	SC	Phase 2 in giant cell arteritis (n=70) complete and positive
Lenzilumab	Humanigen	Q4W	IV only	Positive Phase 3 results in COVID-19 pneumonia



Q = subcutaneous; TV = intravenous. Otilimab and mavrilimumab are being studied as IV formulations in their COVID-19 trials. All trademarks are property of their respective owners.

# Multiple Data Points Converge on GM-CSF as a Target for Pulmonary Sarcoidosis



#### **Pulmonary Sarcoidosis**



- Namilumab's lead indication, pulmonary sarcoidosis, is an autoimmune disease characterized by the accumulation of granuloma nodules in the lungs
- Prevalence is 150-200K patients in the US alone<sup>1</sup>
- 20-30% of patients end up with permanent lung damage<sup>2</sup>

#### **GM-CSF in Sarcoidosis**

- The granulomatous response is believed to begin when an antigen chronically stimulates and activates antigen-presenting cells, including alveolar macrophages
- Macrophages process and present the antigen, leading to the activation of CD4+ helper T cells, which produce pro-inflammatory cytokines including GM-CSF
- GM-CSF has been critically implicated in multiple parts of the granulomatous response, including:
  - Activation and fusion of alveolar macrophages into multinucleated giant cells<sup>3</sup>
  - Priming and maintenance of T cell activation<sup>4,5,6</sup>
  - Interactions between lymphoid and myeloid cells that promote granuloma formation  $^{7.8,9}$
- We plan to study whether namilumab may improve organ function and reduce the usage of steroids, which carry significant side effects when used longer-term

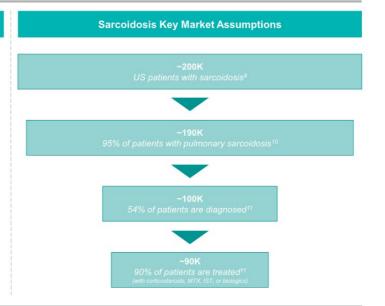


1. Baughman 2016; 2. ATS Patient Education Series 2006; 3. Lemaire 1996; 4. Zhang 2013; 5. Dougan 2019; 6. Shi 2006; 7. Iannuzzi 2007; 8. Becher 2016; 9. Hamilton 2020

#### **Namilumab for Pulmonary Sarcoidosis**

#### **Additional Commentary**

- Corticosteroids are the most widely used treatment for sarcoidosis, but they carry significant side effects when used longer-term and relapses are common when attempting to taper¹
- Immunosuppressive therapy (methotrexate, azathioprine) and biologics (TNF inhibitors) are steroid-sparing second-line and third-line options, but slow onset, safety risks, inconsistent effectiveness, and reimbursement challenges limit their use<sup>2,3</sup>
- There remains significant unmet medical need for patients who are not well-controlled by steroids and/or immunosuppressants (symptomatic and/or unable to tolerate effective doses), which could be met by a novel biologic<sup>4,5</sup>
- Market research estimates ~25% of diagnosed and treated pulmonary sarcoidosis patients would be eligible for treatment with second-line or later therapy<sup>5</sup>
- GM-CSF drives disease progression in a variety of preclinical and clinical trials, including inflammatory arthritis, multiple sclerosis, interstitial lung disease, nephritis, myocarditis, and giant cell arteritis, suggesting multiple indication expansion opportunities<sup>6,7,8</sup>

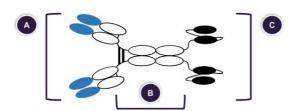




1. Khar 2017; 2. Cremmelin 2016; 3. Beegle 2013; 4. Key Opinion Leader Discussions: 5. HCP market research; 6. Hamilton 2020; 7. Kiniksa Announces Positive Data from Phase 2 Trisl of Mavrillmuraeb in Glant Cell Arteritis 2020; 8. GSK Presents New Efficacy and Safety Data 12 of an Anti GM-CSF Antibody in Patients with Rheumatolid Arthritis 2018; 9. Arkema 2020; 10. Wu 2004; 11. CompileHealth claims data extrapolated to US population.



#### Bispecific Antibodies: A Novel Class that Directs the Immune System to Kill Tumors



Tumor Associated Antigen (TAA) binding domain:
Causes high affinity, high specificity binding to tumor surface

#### Linker region:

Improves pharmaceutical properties. Size and flexibility can be modulated to fine tune activity

Immune cell binding domain:
Binds and activates specific immune cell subsets, resulting in tumor cell death

## Unique Approach to Engaging Natural Killer (NK) Cells and Macrophages Kills Tumor Cells



- Affimed's Innate Cell Engagers (ICE) bind CD16A with a unique epitope
- CD16A is sufficient to fully activate cell killing by NK cells and macrophages
  - · Differentiated from platforms that can engage NK cells
- · Highly selective for CD16A
  - · No dilution and sink effect through neutrophils (CD16B+)
- · High affinity binding with minimal serum IgG competition
  - Superior to monoclonal antibodies (mAbs) and Fc-enhanced mAbs





#### Early preclinical and clinical proof of concept for ROCK platform

#### **ICE Monotherapy**

- In March 2021, Affimed announced positive results from its preplanned interim futility analysis of AFM13 in patients with relapsed or refractory CD30-positive peripheral T-cell lymphoma (PTCL)
- The study will continue and combine cohorts of CD30 high and CD30 low expressing PTCL based on assessment from the Independent Review Committee
- Objective responses were observed in heavily pretreated patients in both cohorts
- The side effect profile observed was similar to previously reported data

#### ICE Co-administered with NK Cells

- In April 2021, Affimed announced preclinical data on AFM24 as monotherapy and in combination with NK cells
- Data from a xenograft mouse model demonstrate that AFM24 in combination with adoptively transferred NK cells results in dosedependent tumor regression

#### CAR-like NK Cells (ICE pre-loaded NK cell)

- In April 2021, Affimed announced positive initial clinical data from a study evaluating NK cells pre-complexed with ICE AFM13
- All four patients experienced significant disease reduction, with two complete responses and two partial responses as assessed by the investigator, with an ORR of 100%
- There were no observed events of cytokine release syndrome, neurotoxicity syndrome or graft-versus-host disease
- Initial results indicate AFM13 may have the potential to help NK cells target and destroy cancer cells



All drugs are investigational and subject to health authority approval.

Source: Affirmed Press Releases, March 10, 2021, April 9, 2021 and April 12, 2021

#### **Affimed Collaboration**



- Affimed's ROCK platform technology generates diverse, tetravalent, bispecific antibodies known as innate cell
  engagers (ICE) which can be customized to target specific binding domains on hematologic and solid tumor cells
- · The partnership grants Roivant a license to AFM32, a preclinical ICE candidate
  - In a head-to-head preclinical study, AFM32's potency exceeded that of a monoclonal antibody that has been clinically validated against the same tumor target
  - AFM32's potency also exceeded that demonstrated in published preclinical studies of an antibody-drug conjugate agent that has been clinically validated against the same tumor target
  - Based on preclinical and clinical experiences with other ICE antibodies in separate studies, the tolerability of AFM32 has the potential to be superior to that observed to date with antibody-drug conjugates in published literature
  - AFM32 is potentially applicable to several highly prevalent solid tumor indications
- Beyond an exclusive license to AFM32, Roivant has the option to license from Affimed additional ICE molecules
  directed against targets that are not (a) currently licensed or optioned to third parties or (b) directed against targets
  included in Affimed's current pipeline



All drugs are investigational and subject to health authority approva



#### Differentiated cellular medicines designed to be uniquely suited to Asian patients



Dr. John L. Xu PRESIDENT

Previously President and CSO of Mab-Legend Biotech; Former CSO of Shanghai Benemae Pharmaceutical Corporation Preclinical

Phase 1 Phase 2

Phase 3

Next Key Milestone

Initiation of CMC activities in 2H 2021



## Cell therapy in hematologic oncology is saturated by CAR-T

Therapeutics in China (in development and launched)

Antigen	CAR-T1
BCMA	24
CD19	88
CD22	18
Total CAR-T <sup>1</sup>	244
Total TCR-T1	46

Asian populations have unique immunological characteristics and specific disease burdens



CVT-TCR-01 Oncologic Malignancies

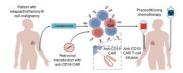


4\*02:07

HLA-A\*02:03

For example, two high-frequency alleles in Southern Chinese (above) are not addressed by any current TCR-based therapy<sup>2,3</sup>

Cell therapy is encumbered by complex manufacturing and regulatory paradigms



For example, production of cellular tissue is highly regulated in China and must be done onshore



TCR-T may better enable solid tumor targeting, a larger market opportunity than blood cancers Asia-specific development focus allows Cytovant to address needs that are unmet by a global focus

Combination of scientific expertise and local knowledge achieves optimal execution



All drugs are investigational and subject to health authority approval.

1. Clarivate Analytics as of January 2021; 2. Cheng L-h et al. J First Mil Med Univ 25:321-324 (2005); 3. Chen KY et al. Immunol Res 53:182-190 (2012).

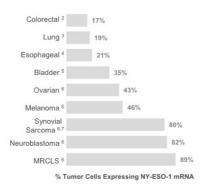
# CVT-TCR-01 (NY-ESO-1): A Clinically Validated Initial Target with Potential Across Multiple Tumor Types



#### NY-ESO-1 is Highly Prioritized in the Scientific Community for Translational Research Opportunities in Cancer<sup>1</sup>

- NY-ESO-1 is an oncofetal protein expressed in malignant tissue; in particular, it is highly expressed in soft tissue sarcoma, ovarian cancer, esophageal cancer, and lung cancer, among others
- NY-ESO-1 is highly immunogenic and its expression is associated with decreased survival
- NY-ESO-1 is only expressed intracellularly, making it a suitable target for a TCR-T based approach

#### NY-ESO-1 is Highly Expressed Across Many Fatal Cancers in Asia



Cancers above resulted in over 1.3 million deaths in 2020 in China alone<sup>8</sup>

#### Promising Preclinical Data and Clinical Validation from Other NY-ESO-1 Directed TCR Therapies

- In preclinical testing, CVT-TCR-01 demonstrated specific and potent killing of NY-ESO-1-positive cell lines as assessed by release of IFN-y, a surrogate for T cell activation and response
- Cytokine release assays indicate that CVT-TCR-01 induces strongly proinflammatory Th1-type cytokine secretion upon exposure to NY-ESO-1 positive cell lines, further supporting CVT-TCR-01's antitumor activity
- Preliminary clinical results from NY-ESO-1 directed TCR therapy demonstrate promising efficacy in a wide variety of tumor types, including synovial sarcoma, multiple myeloma, and myxoid round cell liposarcoma



1. Cheever MA et al. Clin. Cancer Res 15:5323-5337 (2009); 2. Li Y et al. Exp Ther Med 13:3581-3585 (2017); 3. Grah JJ et al. Tumori 100:80-88 (2014); 4. Zhang Y et al. J Cancer Res Clin Oncol 145:281-291 (2019); 5. Dyrskjot L et al. Br.J Cancer 107:116-122 (2012); 6. Thomas R et al. Front Immunol 9:947 (2018); 7. Wang S et al. J Cancer 8:1759-1768 (2017); 8. Calculated from GLOBOCAN 2020 mortality data.

