UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

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

Date of report (Date of earliest event reported): September 17, 2025

Roivant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**001-40782**	**98-1173944**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

7th Floor
50 Broadway
London SW1H 0DB
United Kingdom
(Address of principal executive offices, and Zip Code)

+44 207 400-3347
Registrant's Telephone Number, Including Area Code

Not Applicable
(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 (*see* General Instruction A.2. below):

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

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Shares, $0.0000000341740141 per share	**ROIV**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 17, 2025, Roivant Sciences Ltd. (the "Company") issued a press release announcing positive results from the Phase 3 VALOR study evaluating brepocitinib in dermatomyositis at its subsidiary Priovant Therapeutics. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On September 17, 2025, the Company posted a presentation regarding the results from the Phase 3 VALOR study on the "Events & Presentations" page of its investor relations website at https://investor.roivant.com and will host a conference call and webcast to discuss the results at 8:00 a.m. E.D.T. on September 17, 2025. A copy of the presentation to be used by the Company during the conference call is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The contents of the Company's website referenced in this Current Report on Form 8-K are not incorporated into this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release, dated September 17, 2025.
99.2	Presentation, dated September 17, 2025.
104	Cover Page Interactive Data File (embedded with Inline XBRL document).

SIGNATURES

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.

ROIVANT SCIENCES LTD.

By: /s/ Keyur Parekh
Name: Keyur Parekh
Title: Authorized Signatory

Dated: September 17, 2025

Exhibit 99.1

Roivant and Priovant Announce Positive Phase 3 VALOR Study Results for Brepocitinib in 52-Week Placebo-Controlled Trial in Dermatomyositis (DM)

- Once-daily oral brepocitinib 30 mg demonstrated clinically meaningful and statistically significant improvement compared to placebo on the primary endpoint and all nine key secondary endpoints, including measurements of skin disease, muscle disease, steroid-sparing effect, and rapidity of onset
- On the primary endpoint, brepocitinib 30 mg achieved a week 52 mean Total Improvement Score (TIS) of 46.5 compared to 31.2 for placebo (p=0.0006), even with nearly twice as many patients coming off background steroids on brepocitinib 30 mg compared to placebo
- More than two thirds of brepocitinib 30 mg patients experienced at least a moderate response (TIS≥40), and nearly half experienced a major response (TIS≥60)
- Consistent dose response was seen between 30 mg and 15 mg dose arms, establishing 30 mg dose as optimal in this setting
- Safety profile was consistent with previous clinical trials of brepocitinib and NDA filing is planned for calendar 1H 2026
- Roivant will host an investor call to discuss these updates today, September 17, 2025, at 8:00 a.m. EDT

BASEL, Switzerland, LONDON, NEW YORK and DURHAM, NC, September 17, 2025 (GLOBE NEWSWIRE) – Roivant (Nasdaq: ROIV) and Priovant Therapeutics today announced positive results from the Phase 3 VALOR study evaluating brepocitinib in dermatomyositis (DM).

On the primary endpoint, brepocitinib 30 mg achieved a week 52 mean TIS of 46.5 compared to 31.2 for placebo (p=0.0006). A statistically significant difference between brepocitinib 30 mg and placebo on mean TIS was seen at all time points, including as early as week 4. This result represents the first ever positive outcome for a 52-week placebo-controlled trial in DM, and the first ever positive registrational trial for a targeted therapy in DM.

“Dermatomyositis is an incredibly debilitating autoimmune disease for patients, and we urgently need novel, approved efficacious therapies,” said Dr. Ruth Ann Vleugels, M.D., M.P.H., M.B.A., Heidi and Scott C. Schuster Distinguished Chair in Dermatology, Founding Director of the Autoimmune Skin Disease Center and Connective Tissue Disease Clinics at Brigham and Women’s Hospital and Program Director for the Dermatology-Rheumatology Fellowship at Harvard Medical School. “The VALOR study’s success represents a groundbreaking moment for the dermatomyositis field, and the results reinforce brepocitinib’s potential to serve as a deeply impactful treatment option for a substantial number of dermatomyositis patients once approved.”

Brepocitinib also demonstrated clinically meaningful and statistically significant improvement over placebo on all nine key secondary endpoints. Dose-dependent response between brepocitinib 30 mg and brepocitinib 15 mg was seen consistently across the primary and secondary endpoints.

Approximately 75% of patients entered the VALOR study on background steroids, with a mean baseline dose of 12.2 mg/day in the brepocitinib 30 mg arm and 11.3 mg/day in the placebo arm. Of these patients on background steroids, 62% of brepocitinib 30 mg patients achieved a steroid dose ≤2.5 mg/day by the end of the study (compared to 34% for placebo) and 42% of brepocitinib 30 mg patients were able to come off steroids altogether (compared to 23% for placebo).

Even against this backdrop, clinical improvement in the brepocitinib 30 mg arm was rapid, deep, lasting and broad, both in absolute terms and relative to placebo:

- Brepocitinib demonstrated clinically meaningful and statistically significant improvement relative to placebo on the CDASI (skin), MMT-8 (motor strength) and HAQ-Disability Index (patient questionnaire around daily living activities requiring functional muscle strength, like getting dressed or walking up five steps).
- More than two-thirds of brepocitinib 30 mg patients experienced at least a moderate response (TIS≥40), and nearly half experienced a major response (TIS≥60); of patients who entered the trial with moderate-to-severe skin disease, 44% on brepocitinib 30 mg achieved cutaneous clinical remission by week 52, compared to 21% on placebo.
- Both TIS and CDASI achieved statistically significant separation from placebo as early as week 4 and sustained that separation at every assessment out to one year; median time to a TIS≥40 response was approximately 8 weeks.

The observed brepocitinib 30 mg safety profile was consistent with previous brepocitinib clinical trials. Adverse events of special interest (AESIs), which included malignancy, cardiovascular events, and thromboembolic events, did not occur with greater frequency in the brepocitinib 30 mg arm than the placebo arm.

“We are thrilled with the results of the VALOR study, and I would like to thank all of the patients, investigators, and study site staff who contributed to this important research achievement,” said Ben Zimmer, Priovant CEO. “We are excited to continue working towards the rapid approval of brepocitinib in dermatomyositis and our broader goal of developing brepocitinib as a transformational therapy for multiple highly morbid autoimmune diseases where the need for novel efficacious therapies is greatest.”

“The VALOR study is a hallmark example of what Roivant does best: identify a high value program with a differentiated mechanism of action, focus on creative development plans in indications like DM with high unmet need, and deliver on clinical execution excellence,” said Mayukh Sukhatme, Roivant President and Chief Investment Officer. “I am extremely proud of Roivant’s continued track record with VALOR as the 12th consecutive positive Phase 3 study for the company – an unparalleled achievement and a testament to Roivant’s unrelenting focus on clinical strategy and execution.”

Priovant plans to file an NDA for brepocitinib in dermatomyositis in the first half of 2026.

About Dermatomyositis
Dermatomyositis (DM) is a multi-organ idiopathic inflammatory condition that affects approximately 50,000 adults in the United States. DM is characterized by debilitating muscle weakness and skin lesions. DM-related muscle weakness causes significant impairment to daily living activities, such as walking up stairs, carrying groceries, and getting dressed. Dermatomyositis rashes often affect large portions of a patient’s body including the scalp and are often disfiguring and painful. No targeted therapies are approved for DM, and a majority of patients require high-dose chronic oral corticosteroids.

About the VALOR Study
VALOR was the longest and largest interventional DM study ever conducted, enrolling 241 subjects globally. Subjects were randomized 1:1:1 to brepocitinib 30 mg, brepocitinib 15 mg and placebo, with one-year of double-blind treatment. The primary endpoint was the difference at week 52 between brepocitinib and placebo in mean Total Improvement Score (TIS), a composite endpoint of multiple measures of DM disease activity.

Investor Conference Call Information
Roivant will host a live conference call and webcast at 8:00 a.m. EDT on Wednesday, September 17, 2025, to discuss the Phase 3 results for brepocitinib in dermatomyositis. To access the conference call by phone, please register online using this registration link. The presentation and webcast details are available under "Events & Presentations" in the Investors section of the Roivant website at https://investor.roivant.com/news-events/events. The archived webcast will be available on Roivant's website after the conference call.

About Priovant

Priovant Therapeutics is a biotechnology company dedicated to developing novel therapies for autoimmune diseases with high morbidity and few available treatment options. The company's lead asset is brepocitinib, a dual selective inhibitor of TYK2 and JAK1. Through dual TYK2/JAK1 inhibition, brepocitinib distinctively suppresses key cytokines linked to autoimmunity—including type I IFN, type II IFN, IL-6, IL-12, and IL-23—with a single, targeted, once-daily oral therapy. Brepocitinib recently generated positive Phase 3 data in dermatomyositis, and an NDA submission is planned for the first half of 2026. Brepocitinib is also being evaluated in non-infectious uveitis (Phase 3) and cutaneous sarcoidosis (Phase 2).

About Roivant
Roivant (Nasdaq: ROIV) is a biopharmaceutical company that aims to improve the lives of patients by accelerating the development and commercialization of medicines that matter. Roivant's pipeline includes brepocitinib, a potent small molecule inhibitor of TYK2 and JAK1 in development for the treatment of dermatomyositis, non-infectious uveitis and cutaneous sarcoidosis; IMVT-1402 and batoclimab, fully human monoclonal antibodies targeting FcRn in development across several IgG-mediated autoimmune indications; and mosliciguat, an inhaled sGC activator in development for pulmonary hypertension associated with interstitial lung disease. We advance our pipeline by creating nimble subsidiaries or "Vants" to develop and commercialize our medicines and technologies. Beyond therapeutics, Roivant also incubates discovery-stage companies and health technology startups complementary to its biopharmaceutical business. For more information, visit https://roivant.com.

Roivant Forward-Looking Statements
This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are usually identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "would" and variations of such words or similar expressions. The words may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act.

Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, and statements that are not historical facts, including statements about the clinical and therapeutic potential of our product candidates, the availability and success of topline results from our ongoing clinical trials and any commercial potential of our product candidates following applicable regulatory approvals. In addition, any statements that refer to projections, forecasts or other characterizations of future events, results or circumstances, including any underlying assumptions, are forward-looking statements. Actual results may differ materially from those contemplated in these statements due to a variety of risks, uncertainties and other factors.

Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the Risk Factors section of our filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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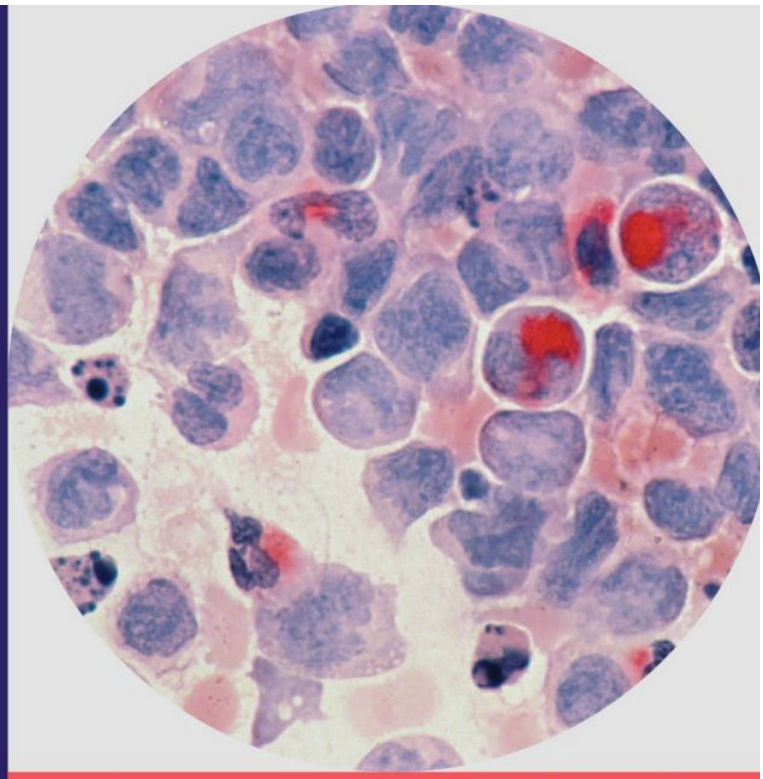
Brepocitinib in DM: VALOR Topline Results



roivant

September 17, 2025

Forward-Looking Statements

This presentation includes forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, potential uses of cash and capital allocation, research and development plans, profitability, the anticipated timing, costs, design, conduct and results of our ongoing and planned preclinical studies and clinical trials for our products and product candidates, and any commercial potential of our products and product candidates are forward-looking statements.

These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this presentation and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements.

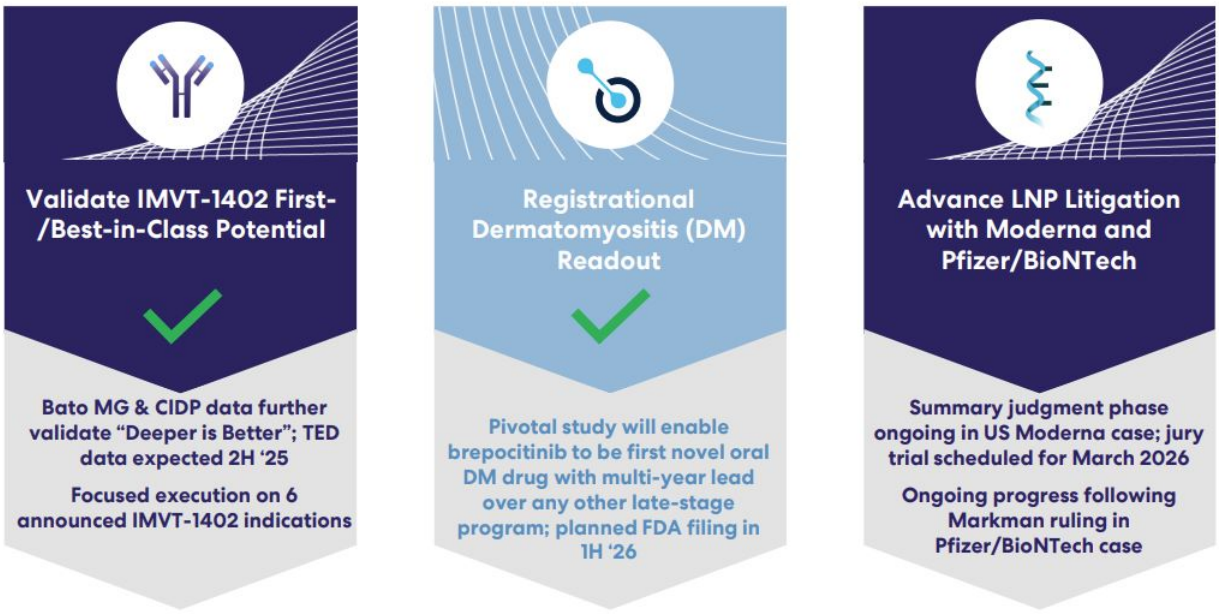
These forward-looking statements may be affected by a number of risks, uncertainties and assumptions, including, but not limited to, those risks set forth in the sections captioned "Risk Factors" and "Forward-Looking Statements" of our filings with the U.S. Securities and Exchange Commission, available at www.sec.gov and investor.roivant.com. We operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this presentation, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

This presentation includes data for brepocitinib as compared to a potential competitor product generated from separate, independent studies and that do not come from head-to-head analyses. Differences exist between study or trial designs and subject characteristics and caution should be exercised when comparing data across studies. Data regarding other products is based on publicly available information.

Disclaimer

This presentation is intended for the investor community only; it is not intended to promote the product candidates referenced herein or otherwise influence healthcare prescribing decisions.

Roivant in 2025: Transformational Potential



Note: All references are to calendar years and are approximate and subject to change. The timing of the litigation-related events noted above is subject to change, including at the discretion of the court. See Slide 2 for further information on these forward-looking statements

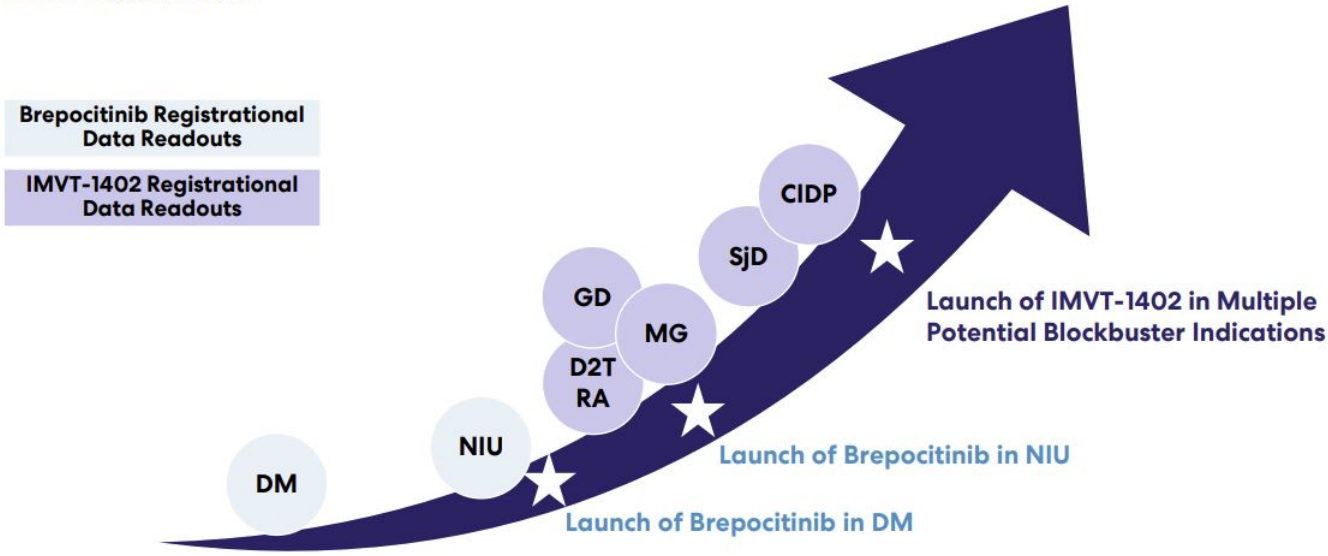
Robust Late-Stage Pipeline with 11 Registrational Trials in Indications with Blockbuster Potential

Focusing on Clinical Trial Execution to Drive Significant Potential Value

	Modality	Proof of Concept	Registrational	Status
BREPOCITINIB Dermatomyositis | *Priovant*	*Small Molecule*		✓	**FDA Filing expected 1H 2026**
BREPOCITINIB Non-Infectious Uveitis | *Priovant*	*Small Molecule*		★	**Actively Enrolling**
BREPOCITINIB Cutaneous Sarcoidosis | *Priovant*	*Small Molecule*	►		**Actively Enrolling**
IMVT-1402 Graves' Disease | *Immunovant*	*Biologic*		★	**Actively Enrolling**
IMVT-1402 Difficult-to-Treat Rheumatoid Arthritis | *Immunovant*	*Biologic*		★	**Actively Enrolling**
IMVT-1402 Myasthenia Gravis | *Immunovant*	*Biologic*		★	**Actively Enrolling**
IMVT-1402 Sjögren's Disease | *Immunovant*	*Biologic*		★	**Actively Enrolling**
IMVT-1402 Chronic Inflammatory Demyelinating Polyneuropathy | *Immunovant*	*Biologic*		★	**Actively Enrolling**
IMVT-1402 Cutaneous Lupus Erythematosus | *Immunovant*	*Biologic*	►		**Actively Enrolling**
BATOCLIMAB Thyroid Eye Disease | *Immunovant*	*Biologic*		★	**Topline expected 2H 2025**
MOSLICIGUAT Pulmonary Hypertension associated with Interstitial Lung Disease | *Pulmovant*	*Inhaled*	►		**Actively Enrolling**
ONGOING BD Pipeline Expansion Opportunities | *Roivant*				

Note: Trials listed as registrational include those that we believe are potentially registrational
Note: All references are to calendar years and are approximate and subject to change. See Slide 2 for further information on these forward-looking statements

Brepocitinib Data in DM Kicks Off 36 Months Stacked with Potential Readouts and Launches



Potential for additional indications and pipeline expansion

Note: Figure is illustrative of potential registrational data readouts and product launches and is not intended to be representative of timelines on the events noted. Trials listed as registrational include those that we believe are potentially registrational

Brepocitinib VALOR Topline Results

priovant therapeutics

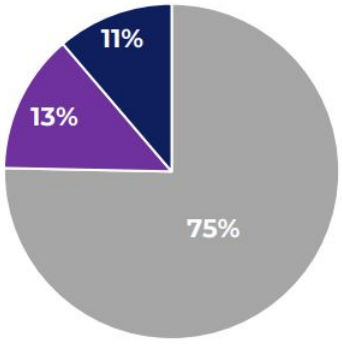
Brepocitinib – Highlights of Phase 3 VALOR Study Results in DM

- **VALOR succeeded, with highly significant, robust, and consistent data across primary and all key secondary endpoints**
- **Consistent dose response seen between 15 mg and 30 mg, establishing 30 mg dose as optimal in this setting**
- **Responses were rapid, deep, and broad, and showed clinically meaningful benefit to both muscle and skin symptoms**
  - **Robust benefit:** Brepocitinib 30 mg showed a mean TIS of 46.5, a delta of >15 points (p=0.0006) relative to placebo at week 52 (TIS of 31.2), even with twice as many patients coming off background steroids on brepocitinib compared to placebo
  - **Depth of response:** >2/3 of brepocitinib 30 mg patients experienced at least a moderate response (TIS40), and nearly half experienced a major response (TIS60)
  - **Rapidity of response:** Onset was rapid with median time to a TIS40 response of ~2 months; TIS and CDASI responses significant as early as week 4
  - **Breadth of response:** Positive data on all 10 pre-specified endpoints demonstrating improvement in both skin and muscle symptoms
- **Brepocitinib 30 mg safety profile in VALOR was consistent with prior clinical studies**
- **FDA filing planned for calendar 1H 2026**

TIS: Total Improvement Score
CDASI-A: Cutaneous Dermatomyositis Activity and Severity Index - Activity Subscore
Product candidate is investigational and subject to regulatory approval. Timing is based on current expectations and subject to FDA feedback

DM Patients Have Significant Unmet Medical Needs

Therapies Received by Treated DM Patients



- **Steroids & ISTs Alone**
- **IVIG-Containing Regimens**
- **Off-Label Targeted Therapy-Containing Regimens (No IVIG)**

- **Standard-of-care in DM is largely unchanged since the 1980s**: combinations of corticosteroids and off-label ISTs
- Patient and physician need for modern, targeted therapies is extraordinarily high given that **unapproved targeted therapies with no RCT data (including JAK inhibitors) are used off-label at rates comparable to IVIg**
- Even among patients treated with IVIg or off-label targeted therapies, chronic high-dose steroid use remains high, **with most requiring doses ≥10 mg/day for ≥100 days/year**

DM: Dermatomyositis
IST: Immunosuppressive therapy
IVIG: Intravenous immunoglobulin
RCT: Randomized controlled trial

Data Source: Analysis by Roivant/Priovant using closed claims data from Inovalon. Analysis includes patients with DM with continuous enrollment from 2020-2022. Conclusions corroborated through independent Veeva Compass open claims data through 2024.

VALOR Study Success Represents a Landmark Achievement in Dermatomyositis Field

Extensive track record of failure for targeted therapies in dermatomyositis, even among approved drugs that are blockbusters in other I&I indications

- Rituxan (Rituximab) — Failed in DM and PM
- Remicade (Infliximab) — Failed in DM and PM
- Stelara (ustekinumab) — Failed in DM and PM
- Ultomiris (ravulizumab-cwvz) injection for intravenous use 300 mg/3 mL vial — Failed in DM
- Enbrel (etanercept) — Failed in DM and PM
- Benlysta (belimumab) — Failed in DM and PM
- Actemra (tocilizumab) — Failed in DM and PM
- Orencia (abatacept) — Failed in DM, PM, and IMNM

Brepocitinib

Oral once-daily selective inhibitor of TYK2 and JAK1

- ✓ **First** successful registrational trial for a targeted therapy in DM
- ✓ **First** successful 52-week placebo-controlled trial for any therapy in DM
- ✓ **First** successful placebo-controlled trial of any kind for a once-daily oral therapy in DM
- ✓ **Largest** interventional DM trial ever conducted, including other ongoing trials

DM: Dermatomyositis
PM: Polymyositis
IMNM: Immune-mediated necrotizing myopathy

Brepocitinib Inhibits both TYK2 and JAK1, Making It Particularly Well-Suited to Address Underlying DM Pathobiology

Pathogenic Cytokine	Role in DM Pathogenesis		Brepocitinib	Selective JAK1 Inhibitor	Selective Tyk2 Inhibitor	Type I IFN Antibody
Type I IFN (IFNα/β)	**Lymphocyte Activation**		✓✓	✓	✓	✓✓
Type II IFN (IFNγ)	**Th1** Lymphocyte Polarization		✓	✓	✗	✗
IL-12			✓	✗	✓	✗
IL-6	**Th17** Lymphocyte Polarization	**B Cell Activation**	✓✓	✓	Partial	✗
IL-23			✓	✗	✓	✗

Brepocitinib 30 mg Achieved Statistically Significant Benefit On All Ten Ranked Endpoints

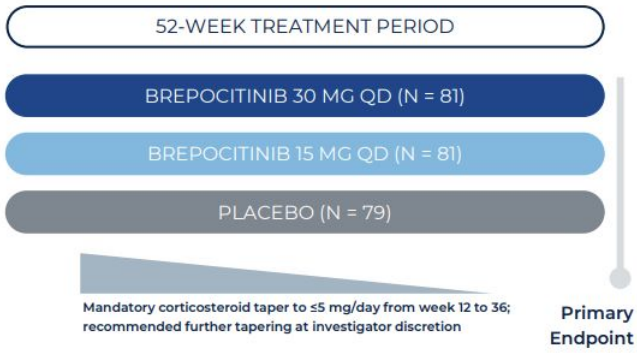
Measurements of skin disease, muscle disease, rapidity of onset, and steroid sparing; consistent dose response was also seen across endpoints

Key Endpoint	Important Features	P-Value
Mean TIS (Primary)	Composite endpoint, focus on **muscle disease** and **global** benefit	**0.0006**
CDASI-A change from baseline at Week 52	Improvement in **skin disease** activity	**0.0006**
DMOMS at Week 52	DM-specific **muscle and skin** composite measure of benefit	**0.0014**
TIS40 Response at Week 52	Moderate TIS response (focus on **global benefit / muscle**)	**0.0040**
Time to Consecutive TIS40 Response by Week 52	**Time to onset of sustained benefit** (particularly high bar)	**0.0155**
Patients achieving TIS40 Response + ≤2.5 mg OCS at Week 52	Achievement of clinical response and **steroid reduction**	**0.0006**
CDASI-A 40% Response with ≥4-point improvement at Week 52	Clinically meaningful **skin response**	**0.0357**
TIS60 Response at Week 52	Major TIS response – **Highest TIS response threshold**	**0.0126**
Change from baseline in HAQ-DI at Week 52	Improvement in physical and functional disability and daily living activities related to **muscle** strength	**0.0035**
Change from baseline in CDASI-A at Week 4	**Rapid onset** of skin response	**0.0003**

VALOR: Global Phase 3 Placebo-Controlled Study Evaluating Brepocitinib In Dermatomyositis

N=241 adults with dermatomyositis

Randomized 1:1:1 by PhGA-VAS



Eligible Patients

- Definite or probable dermatomyositis (2017 EULAR/ACR criteria)
- Skin activity: CDASI-A ≥6
- Muscle activity: MMT-8 ≤142
- Refractory or intolerant to SOC therapy

Permitted Background Therapy

Oral IST, antimalarial, and/or OCS

Primary Endpoint

30 mg vs. placebo mean Total Improvement Score at Week 52

IST: Immunosuppressive therapy
OCS: Oral corticosteroids
CDASI-A: Cutaneous Dermatomyositis Activity and Severity Index - Activity Subscore
MMT-8: Manual testing of 8 muscle groups
SOC: Standard of care
PhGA-VAS: Physician's Global Assessment – Visual Analog Scale

Enrolled Population Had Highly Active, Multisystem Disease

Arms were well-balanced across demographics, baseline disease activity, and background medications

	Brepocitinib 30 mg (n = 81)	Brepocitinib 15 mg (n = 81)	Placebo (n = 79)
Mean Age (years) (± SD)	50.4 (14.5)	50.7 (12.1)	50.7 (13.5)
Sex (Female) – no. (%)	65 (80%)	67 (83%)	55 (70%)
Region: US/Canada – no. (%)	32 (40%)	34 (42%)	30 (38%)
Disease Activity – no. (%)			
Mild	13 (16%)	19 (24%)	13 (16%)
Moderate	54 (67%)	40 (49%)	48 (61%)
Severe	14 (17%)	22 (27%)	18 (23%)
Mean MMT-8 Score (± SD)	121.7 (16.4)	124.5 (14.2)	121.6 (17.0)
Mean CDASI-A Score (± SD)	19.5 (11.3)	18.7 (11.3)	21.1 (12.0)
History of ILD – no. (%)	19 (24%)	17 (21%)	11 (14%)
Medications at Baseline – no. (%)			
Immunosuppressant	55 (68%)	57 (70%)	61 (77%)
Antimalarial	24 (30%)	22 (27%)	19 (24%)
Corticosteroids	60 (74%)	58 (72%)	64 (81%)
Mean dose (mg/day) (± SD)	12.2 (5.7)	10.7 (6.2)	11.3 (5.9)

MMT-8: Manual muscle testing of 8 muscles
CDASI-A: Cutaneous Dermatomyositis Activity and Severity Index - Activity Subscore
ILD: Interstitial lung disease

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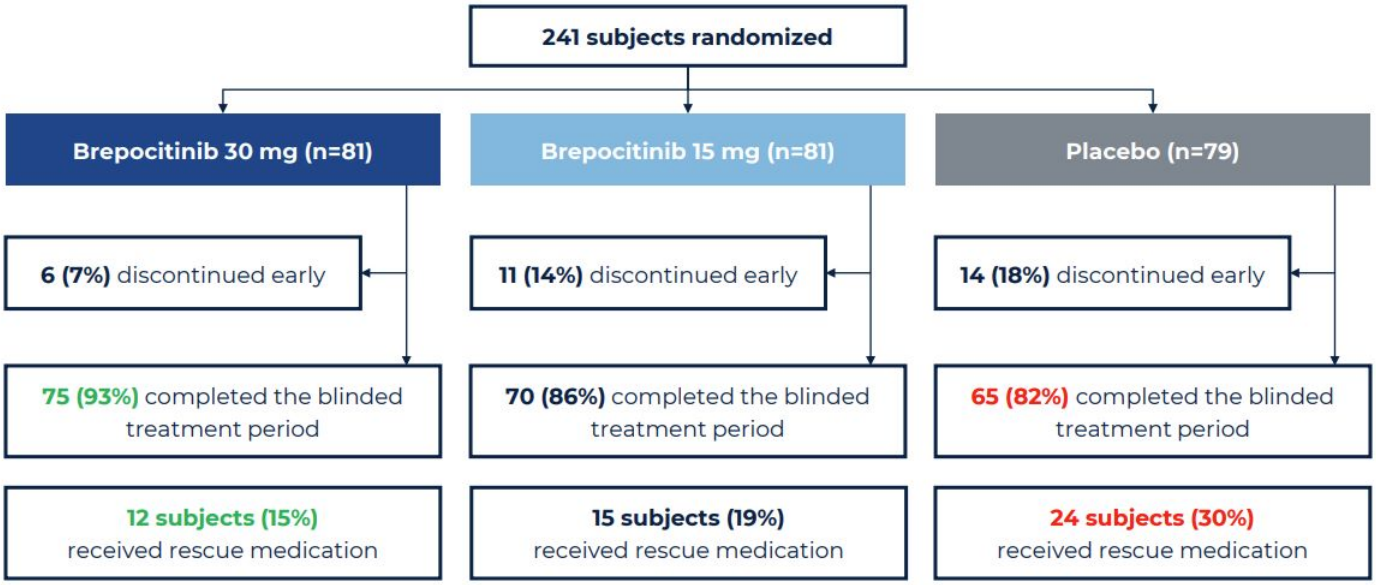
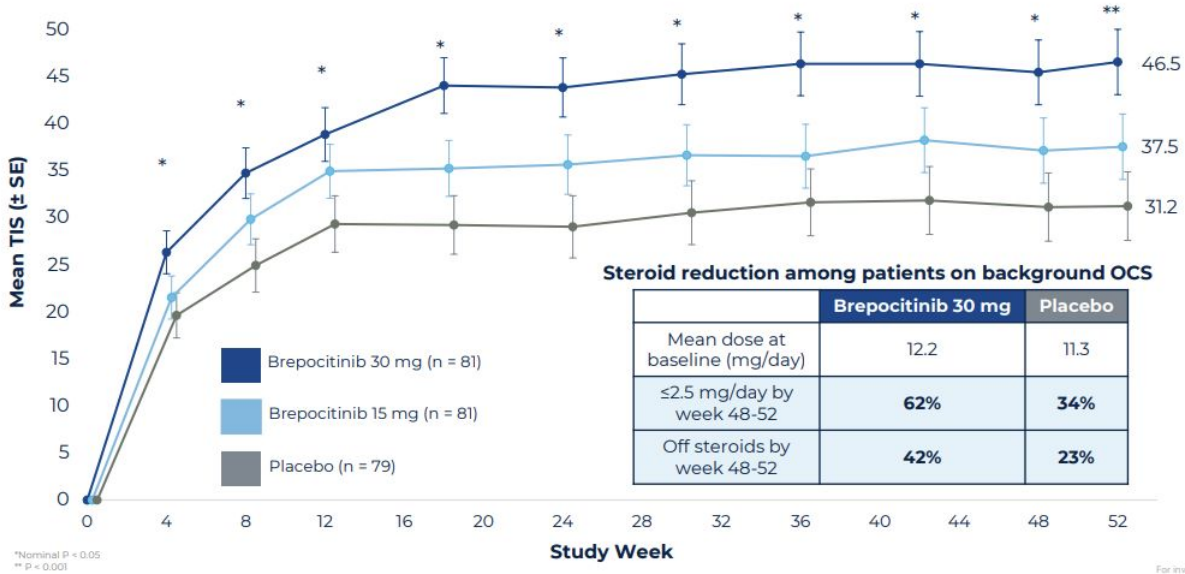
Disposition: Brepocitinib Had Substantially Higher Completion Rate and Substantially Lower Rescue Rate Than Placebo



The definition of rescue medication was prespecified. This included initiation or clinically-meaningful increase in intensity of one or more systemic therapies given for treatment of DM.

Brepocitinib Showed Significant and Clinically Meaningful Improvement on Primary Endpoint of TIS

Separation between brepocitinib 30 mg and placebo at all time points, starting as early as week 4, achieved together with substantially greater steroid reduction in brepocitinib 30 mg arm



Steroid reduction among patients on background OCS

	Brepocitinib 30 mg	Placebo
Mean dose at baseline (mg/day)	12.2	11.3
≤2.5 mg/day by week 48-52	**62%**	**34%**
Off steroids by week 48-52	**42%**	**23%**

Primary Endpoint

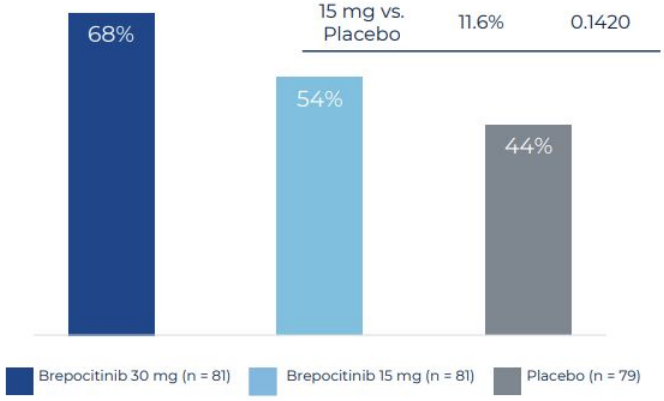
30 mg vs. Placebo
At Week 52
TISΔ 15.3
P = 0.0006

*Nominal P < 0.05
** P < 0.001

>2/3 of Patients on 30 mg Achieved Moderate TIS Response (TIS40) & Nearly Half Achieved Major TIS Response (TIS60)

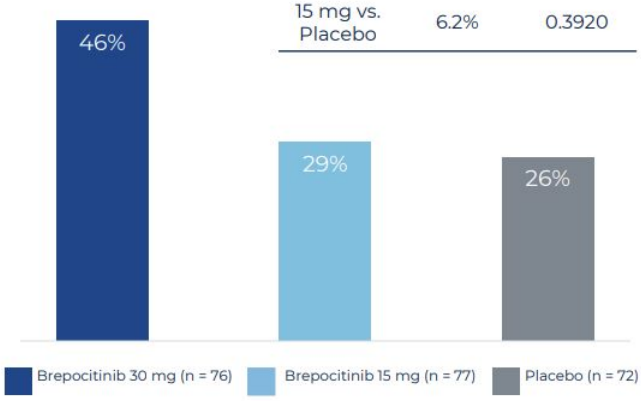
Patients Achieving Moderate TIS Response (TIS40) at Week 52

	Δ	P
30 mg vs. Placebo	**22.2%**	**0.0040**
15 mg vs. Placebo	11.6%	0.1420



Patients Achieving Major TIS Response (TIS60) at Week 52

	Δ	P
30 mg vs. Placebo	**19.5%**	**0.0126**
15 mg vs. Placebo	6.2%	0.3920



Adjusted response rate (risk) differences calculated using the Mantel-Haenszel method.

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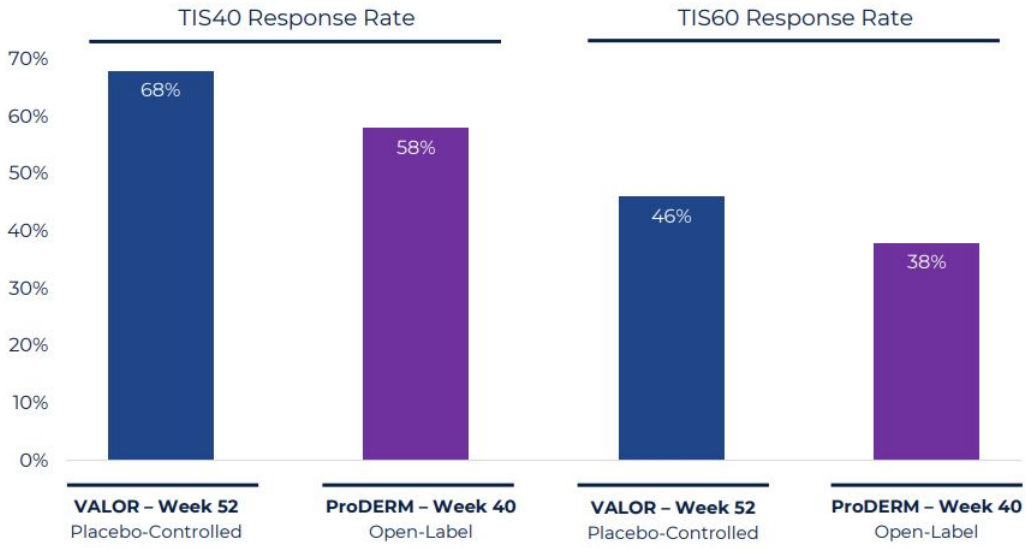
Brepocitinib 30 mg Resulted in High Rates of Clinically Meaningful Improvement

Cross-Trial Comparison of TIS Responder Rates At Similar Timepoints



Brepocitinib 30 mg (n = 81)

Octagam (IVIg) (n = 45)[1]

Disclaimer: Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.

1) Aggarwal et al, NEJM 2022

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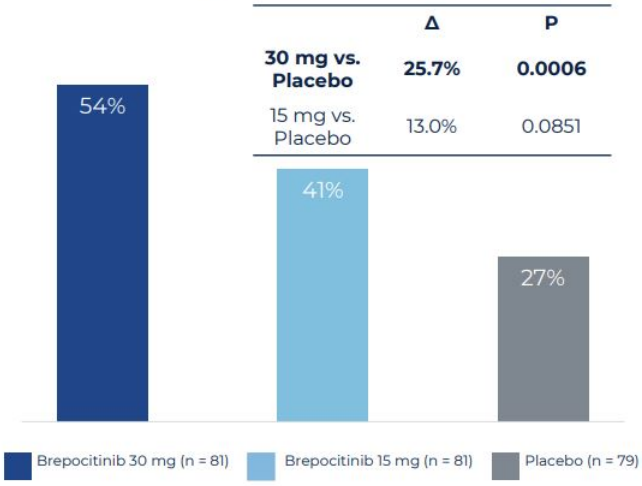
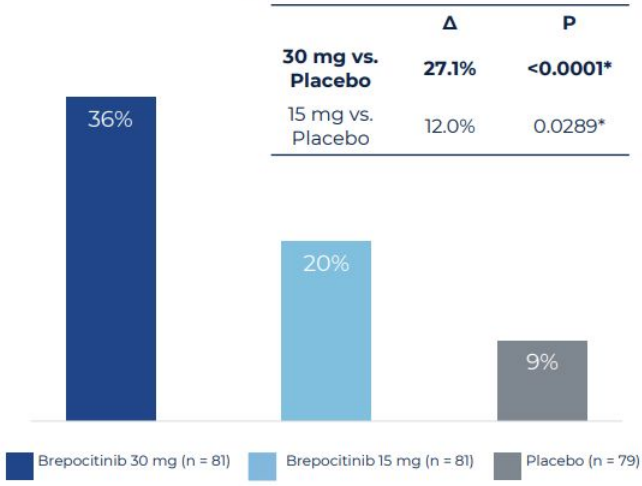
More Than A Third of Brepocitinib 30 mg Patients Achieved Both Major TIS Response And Minimal or No Steroid Burden At Week 52

Patients Achieving Moderate TIS Response (TIS40) with Oral Steroids ≤2.5 mg/day at Week 52



	Δ	P
30 mg vs. Placebo	**25.7%**	**0.0006**
15 mg vs. Placebo	13.0%	0.0851

Patients Achieving Major TIS Response (TIS60) with Oral Steroids ≤2.5 mg/day at Week 52

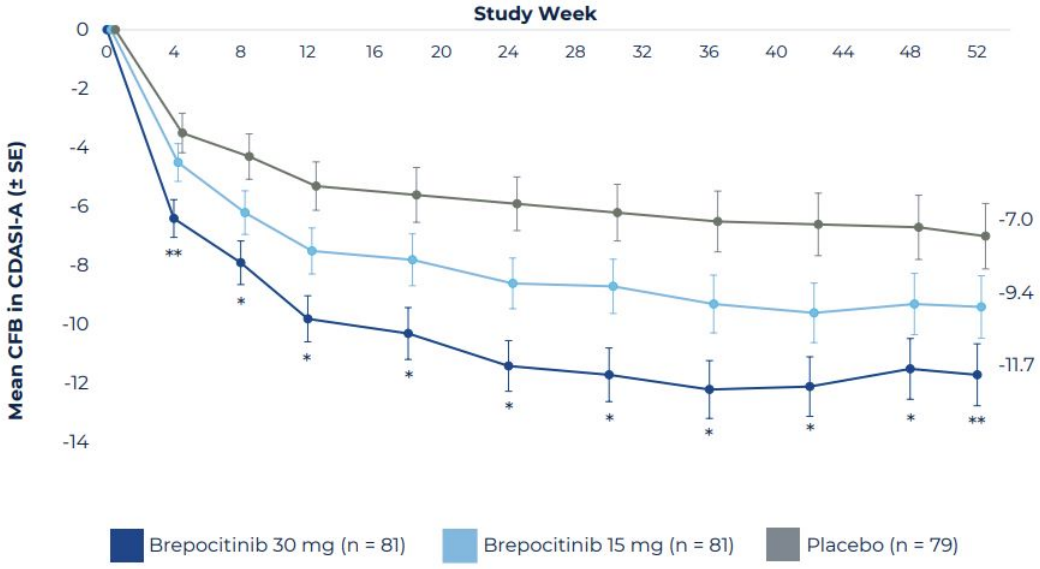


	Δ	P
30 mg vs. Placebo	**27.1%**	**<0.0001***
15 mg vs. Placebo	12.0%	0.0289*

*Nominal p-value calculated as part of post-hoc analysis
Adjusted response rate (risk) differences calculated using the Mantel-Haenszel method.

Time Course of CDASI-Activity Change from Baseline

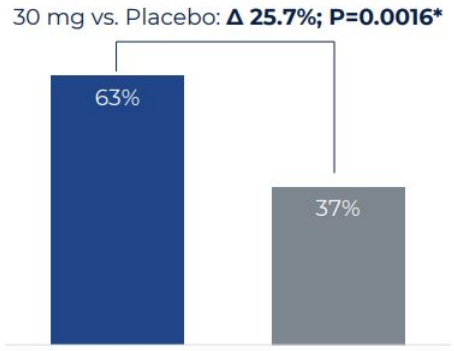
Statistically significant, clinically meaningful separation between brepocitinib 30 mg and placebo at all time points, starting as early as week 4



*Nominal P < 0.05
** P < 0.001

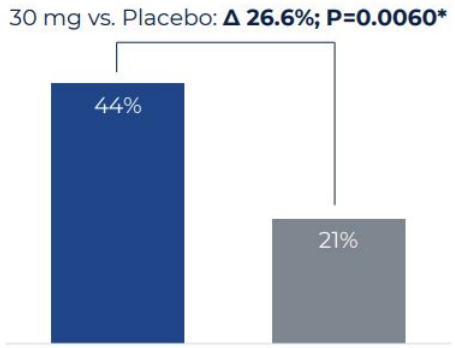
Brepocitinib 30 mg Achieved Meaningful Cutaneous Improvement in Subjects with Moderate-to-Severe Skin Disease at Baseline

Highly morbid, often treatment-resistant population representing significant share of DM patients



Mean Percent Reduction in CDASI-A by Week 52

Subjects with baseline CDASI-A > 14



Portion of Patients Achieving Cutaneous Clinical Remission by Week 52 (CDASI-A ≤ 5)

Subjects with baseline CDASI-A > 14

Ns for subjects with moderate-to-severe skin disease at baseline: brepocitinib 30 mg n = 46; placebo n = 53
*Nominal p-value calculated as part of post-hoc analysis

CDASI-A: Cutaneous Dermatomyositis Activity and Severity Index - Activity Subscore

Brepocitinib 30 mg Demonstrated Substantial Evidence of Improvement on Muscle Disease Across Multiple Endpoints

Global Benefit

Substantial Improvement on TIS in Patients with Moderate-to-Severe Muscle Disease at Baseline

+17 points

vs. Placebo in patients with MMT-8 < 136 at baseline[1]

72% on brepocitinib 30 mg achieved TIS40 in this subgroup, versus 46% on placebo

Motor Strength

Confirmed Benefit on MMT-8 with Brepocitinib 30 mg vs. Placebo

13.5 vs. 8.7

Δ 4.8, P=0.04[2]

72% on brepocitinib 30 mg achieved 7-point increase[3], compared to 54% on placebo

Functional Muscle Improvement

HAQ-Disability Index Achieved Clinical and Statistical Significance

-.30 points

vs. Placebo, P = 0.0035

49% on brepocitinib 30 mg achieved the MCID of at least -0.3, compared to 29% on placebo

1. Based on a post-hoc analysis
2. Nominal P value
3. 7-point change on the MMT-8 score represents 1 category of muscle disease activity (i.e., moderate vs. mild disease).

MCID: Minimum clinically important difference

Brepocitinib 30 mg Achieved Rapid Onset Of Action, With Confirmed Benefit As Early As Week 4

Rapid onset of action consistent with TYK2/JAK1 mechanism of action

Rapid Statistically Significant Separation From Placebo

Week 4

Time to achieve statistically significant separation on both TIS* and CDASI-A for brepocitinib 30 mg vs. placebo

Rapid Achievement of Clinical Improvement Thresholds

32 days

Median Time to TIS20

61 days

Median Time to TIS40

TIS: Total Improvement Score;
CDASI-A: Cutaneous Dermatomyositis Activity and Severity Index - Activity Subscore
*Based on nominal p value.

Brepocitinib 30 mg Achieved Statistically Significant Benefit On All Ten Ranked Endpoints

Measurements of skin disease, muscle disease, rapidity of onset, and steroid sparing; consistent dose response was also seen across endpoints

Key Endpoint	Important Features	Brepocitinib 30mg (n=81)	Placebo (n=79)	P-Value
Mean TIS (Primary)	Composite endpoint, focus on **muscle disease** and **global** benefit	46.5	31.2	**0.0006**
CDASI-A change from baseline at Week 52	Improvement in **skin disease** activity	-11.7	-7.0	**0.0006**
DMOMS at Week 52	DM-specific **muscle and skin** composite measure of benefit	57.9	40.5	**0.0014**
TIS40 Response at Week 52	Moderate TIS response (focus on **global benefit / muscle**)	67.9%	44.3%	**0.0040**
Time to Consecutive TIS40 Response by Week 52	**Time to onset of sustained benefit** (particularly high bar)	85 days	168 days	**0.0155**
Patients achieving TIS40 Response + ≤2.5 mg OCS at Week 52	Achievement of clinical response and **steroid reduction**	54.3%	26.6%	**0.0006**
CDASI-A 40% Response with ≥4-point improvement at Week 52	Clinically meaningful **skin response**	61.7%	44.3%	**0.0357**
TIS60 Response at Week 52	Major TIS response – **Highest TIS response threshold**	46.1%	26.4%	**0.0126**
Change from baseline in HAQ-DI at Week 52	Improvement in physical and functional disability and daily living activities related to **muscle** strength	-0.337	-0.042	**0.0035**
Change from baseline in CDASI-A at Week 4	**Rapid onset** of skin response	-6.4	-3.5	**0.0003**

Overview of Safety Events

	Brepocitinib 30 mg QD (N=81)	Brepocitinib 15 mg QD (N=81)	Placebo (N=79)
Participants with:			
AEs	73 (90%)	70 (86%)	72 (91%)
Death	0	0	0
SAEs	13 (16%)	7 (9%)	10 (13%)
AEs leading to treatment discontinuation	5 (6%)	6 (7%)	9 (11%)
AEs leading to study discontinuation	3 (4%)	4 (5%)	3 (4%)
Adverse Events of Special Interest:			
Cardiovascular events	1 (1%)	0	2 (3%)
Thromboembolic events	0	0	1 (1%)
Viral reactivation	4 (5%)	2 (2%)	4 (5%)
Opportunistic infections	0	0	0
New or recurrent diagnoses of malignancy	0	0	2 (3%)
Increase in ALT or AST	1 (1%)	2 (2%)	1 (1%)

- Adverse events of special interest balanced across treatment arms; no new safety signals for brepocitinib
- Brepocitinib safety database includes over 1,500 patients and subjects, with a safety profile that appears consistent with approved JAK inhibitors

Abbreviations: AE=adverse event, ALT=alanine aminotransferase, AST=aspartate aminotransferase, SAE=serious adverse event.
Note: Percentages are based on the number of unique participants with an event out of the column total. Treatment-emergent AEs are reported.

VALOR Results Confirm Brepocitinib's Potential to Meaningfully Improve the Lives of Patients with DM

	Breadth of Response	Depth of Response	Speed of Response	Safety
Observed Results in VALOR	✓ Statistically and clinically significant improvement in skin disease ✓ Statistically and clinically significant improvement in muscle disease	✓ High TIS response rates even while aggressively tapering steroids ✓ Functional remission of skin disease achieved in nearly half of subjects with moderate-to-severe disease at baseline	✓ Confirmed benefit on TIS and CDASI as early as week 4 ✓ Median Time to TIS40 of 8 weeks	✓ Safety database of >1,500 patients ✓ Adverse events of special interest balanced across treatment arms; no new safety signals for brepocitinib
Implication for Patients	**Nearly all DM patients can potentially benefit from brepocitinib**	Significant fraction of patients can potentially achieve **deep, clinically meaningful responses**	Patients can potentially achieve **rapid improvement in symptoms** in as few as 4 weeks	Potentially **favorable benefit:risk** profile for patients

Results achieved with a convenient once-daily oral therapy

TIS: Total Improvement Score
CDASI-A: Cutaneous Dermatomyositis Activity and Severity Index - Activity Subscore

Upcoming Roivant Investor Day

Thursday, December 11th, 2025
In-Person

Details to follow

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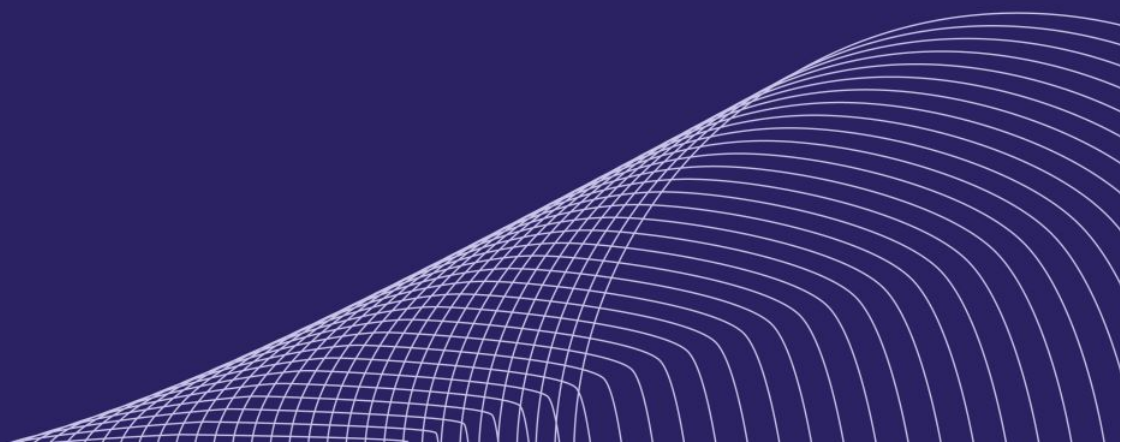
Q&A



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Appendix

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Dermatomyositis: Disease Overview

Dermatomyositis is a chronic inflammatory disease of the skin and muscles that affects approximately 40-50K US adults

US ADULT PREVALENCE

INCIDENCE

1. Smoyer-Tomic et al, BMC Musculoskeletal Disorders (2012)
2. Reeder et al, Arch Dermatol (2010)
3. Kronzer et al, Arth Care Res (2021)
4. Osman et al, Sci Reports (2023)

Brepocitinib: Other Details

Ownership	ROIV owns 74%[1] of Priovant, with Pfizer owning 25%.
Geographic Rights	Priovant has commercial rights to brepocitinib in US and Japan.
Intellectual Property	We expect Brepocitinib to have US exclusivity at least until 2039[2].
Milestones	Priovant is obligated to pay Pfizer mid tens-of-millions if sales exceed a mid hundreds-of-millions amount in Priovant territories. Pfizer is obligated to pay Priovant low tens-of-millions if sales exceed a mid hundreds-of-millions amount in non-Priovant territories.
Royalties	Priovant is obligated to pay Pfizer tiered sub-teens royalties on annual sales in Priovant territories. Pfizer is obligated to pay Priovant tiered high single digits to sub-teens royalties on annual sales in non-Priovant territories.

1. As of June 30, 2025. 65% on a fully diluted basis.
2. Includes potential patent term extension

Speaker Biographies

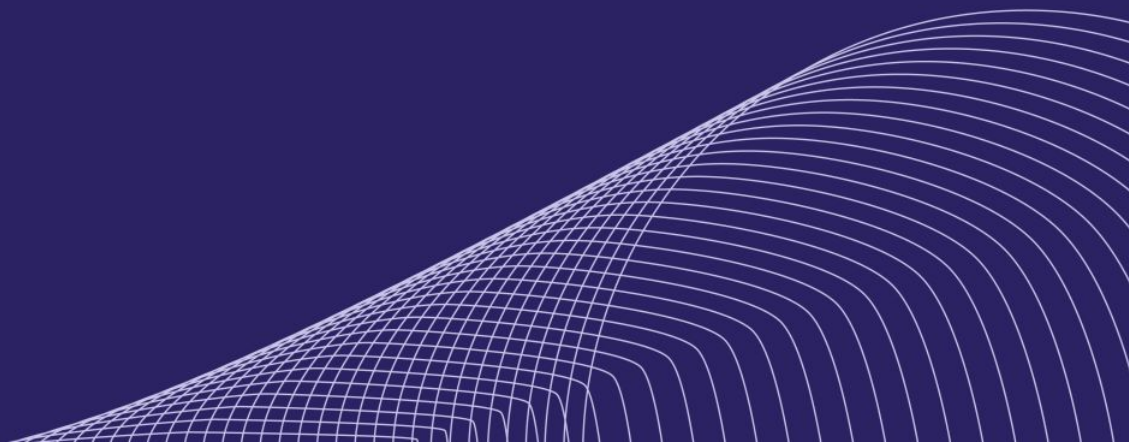
Matthew Gline

Matt Gline serves as Chief Executive Officer of Roivant Sciences. Mr. Gline joined Roivant in March 2016 and previously served as Chief Financial Officer. From April 2014 to March 2016, he 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. From 2008 to 2012, he served as Vice President at Barclays, Enterprise Risk Management Advisory, where he provided analysis for corporate clients related to capital markets access for financing and risk management. Mr. Gline earned his A.B. in Physics from Harvard College.

Benjamin Zimmer

Ben Zimmer has been CEO of Priovant since the company's creation in 2021. Prior to joining Priovant he served on the leadership team of Roivant as acting COO (2018-2019) and President, Roivant Health (2018-2021). In this role, Ben led the incubation, launch, and board oversight of Datavant (majority stake acquired by New Mountain Capital), Sinovant (included in Roivant-DSP transaction), and VantAI. From 2015-2018, Ben worked at Roivant in a variety of roles across business operations, clinical operations, and public affairs. Before Roivant, Ben founded and ran a public policy-focused non-profit and worked as a consultant at McKinsey. He holds an A.B. in History from Harvard College and a J.D. from Yale Law School.

Thank you.



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