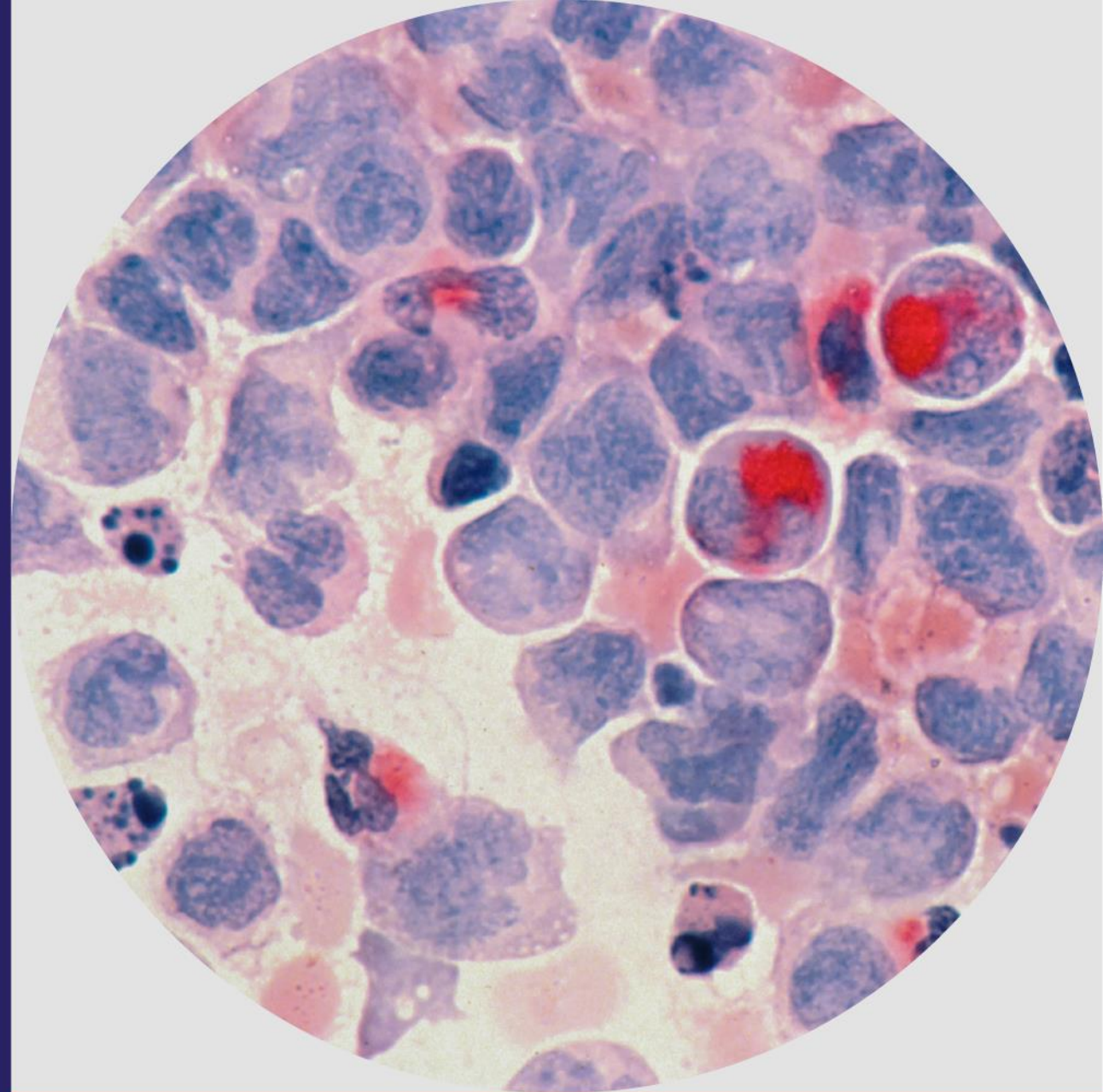


# Unveiling New Pipeline Program: Mosliciguat at Pulmovant

roivant



September 10, 2024

# Speakers



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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](http://www.sec.gov) and [investor.roivant.com](http://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, results, and attributes for mosliciguat and certain other products and product candidates generated from separate, independent studies and that do not come from head-to-head analysis. Differences exist between study or trial designs

and subject characteristics and caution should be exercised when comparing data across studies. Data regarding other products and product candidates 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.

# 2024 Is a Year of Expansion for Roivant



**Deliver Clinical Data for Leading Anti-FcRn Franchise and Announce Development Plans for 1402**

Anticipate that deeper IgG suppression may lead to greater efficacy across multiple indications with data from batoclimab to inform IMVT-1402 trial designs



**Advance Clinical Development In a Range of Underappreciated Pipeline Opportunities**

Initiate brepocitinib Phase 3 program in NIU and mosliciguat Phase 2 program in PH-ILD; namilumab Phase 2 readout to inform portfolio prioritization



**Expand VTAMA Label with AD & Accelerate PsO Revenue Growth**

sNDA filed with FDA PDUFA action expected 4Q 2024; accelerate PsO revenue growth through script expansion and GTN yield accretion



**Expand Pipeline Through Mid-Late-Stage Business Development**

Bolster pipeline through creative, win-win deals with partners, enabled by execution track record and strong balance sheet



**Prioritize Capital Allocation towards Best Value Creation Opportunities**

Plan to be prudent and thoughtful deploying capital; will prioritize optimizing shareholder base for next era of Roivant growth

# Moslicigat Expands Roivant's Long-Term Growth Optionality with the Addition of Another Therapeutic Area to Existing \$10BN+ I&I Pipeline

Adds another meaningful potential medicine to Roivant's pipeline for patients suffering from a disease with high mortality, low quality of life and limited treatment options

**2024-2026**

**Multiple new approvals, 6+ Phase 2 or 3 data readouts including multiple registrational data sets each year, and pipeline additions**

**2026-2030**

**Wave of potential additional approvals across large established I&I and untapped high-value growth markets**

**2030+**

**Multiple blockbuster products with \$10BN+ aggregate peak revenue potential across I&I; moslicigat expands potential in a new therapeutic area**

# Unveiling New Pipeline Program: Mosliciguat

**roivant**

A decorative graphic in the bottom right corner consisting of a grid of thin red lines. The grid is composed of vertical and horizontal lines that curve and warp as they move towards the right, creating a sense of depth and movement. The lines are more densely packed on the left and become more sparse and curved on the right.

# Mosliciguat: Phase 2-Ready Inhaled, Once-Daily, Soluble Guanylate Cyclase (sGC) Activator with Potential to Transform Pulmonary Hypertension (PH)

## Mosliciguat has Potential to be First-in-Class

- Mosliciguat is an inhaled sGC activator specifically designed for lung-targeted effects
- sGC pathway activation results in vasodilatory, anti-inflammatory and anti-fibrotic effects
- Unlike sGC stimulators, mosliciguat does not require heme or NO to work and retains efficacy even in conditions associated with oxidative stress

## Large and Well-Validated Market Opportunity

- Focusing initially on high unmet need in pulmonary hypertension associated with interstitial lung disease (PH-ILD), a large population with limited or no treatment options
- Imminently initiating a Phase 2 study in PH-ILD – optimized trial design/ patient population maximizes POS

## Compelling Clinical Data in Phase 1b ATMOS study

- Some of the highest reductions to date in pulmonary vascular resistance (PVR)<sup>1</sup>
- Favorable safety profile with no clinically relevant changes seen in systemic vascular resistance or blood pressure
- Phase 1b (n=38) data, including PVR reductions, were presented at European Respiratory Society (ERS) Congress
- Robust and well-characterized program, with safety database of 170 subjects to date

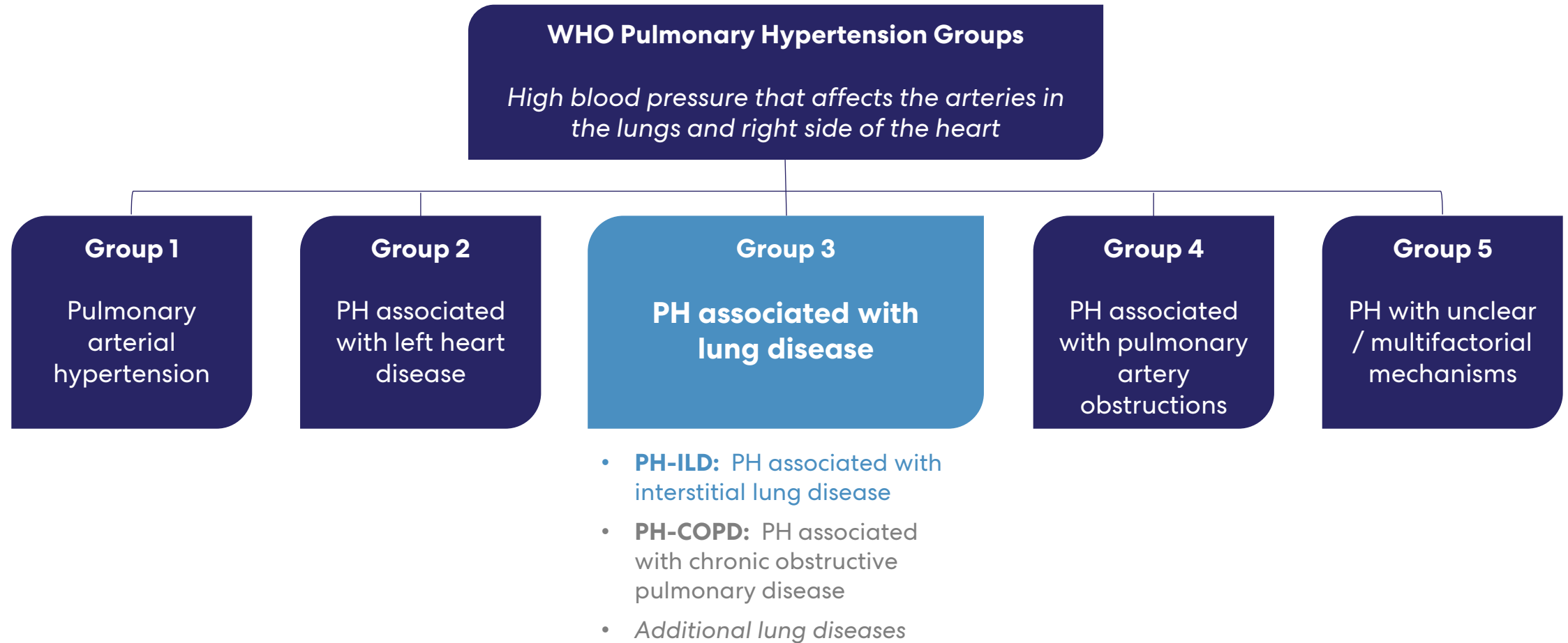
## Differentiated Dosing Profile

- ~40-hour half-life allows convenient, one puff per day dosing with a dry powder inhaler (DPI)
- Targeted delivery directly to lungs reduces risk of systemic side effects

## Favorable Transaction Structure with Strong IP

- Global rights licensed from Bayer for \$14M upfront and up to \$280M in development, regulatory, and commercial milestones, and tiered high-single digit royalties
- Granted patents and pending applications, if issued, provide protection out to 2042, before potential PTE

# Initially Focusing on Group 3, PH Associated with Lung Disease; Potential for Multiple Other PH Expansion Opportunities





# PH-ILD Patients Have Limited Treatment Options with Reduced Quality of Life and Less Than 5-Year Median Survival



**PH-ILD is a particularly severe subgroup of PH<sup>1</sup>**

- Lung disease is the second most common cause of PH<sup>1</sup>
- Structural lung changes and chronic hypoxia lead to pulmonary vascular remodeling and PH in ILDs<sup>2</sup>

*“Even if progression of ILD seems to be slowing with the antifibrotics, I am pretty aggressive with treatment given how fast they can decline when PH is present.” - Physician*



**< 5-year median survival<sup>3</sup>**

- Compared to patients with PAH, PH-ILD patients have<sup>3</sup>:
  - Increased risk of mortality & morbidity
  - Reduced functional capacity and health related QoL
- Elevations in PVR are associated with worse mortality in PH-ILD patients<sup>4</sup> – reducing PVR should improve outcomes

*“My medical problems are consuming my everyday life.” - PH-ILD patient*



**Limited or no approved treatment options**

- No approved therapies in major ex-US markets
- Only 1 approved therapy in the US, which requires 4x daily dosing and causes cough in patients whose lungs are already compromised
- Other than inhaled treprostinil, Group 1 PH drugs have generally not shown clinical benefit in patients with Group 3 PH<sup>5</sup>

*“Efficacy [of approved therapy] is not amazing ... it’s all we have, but there is definitely room to improve.” - Physician*

1. Humbert et al., European Heart Journal, 2022







2. Kacprzak et al., Diagnostics, 2023

3. Nikkho et al., Pulm Circulation, 2022; Klinger et al., Cardiol Clin., 2016; Hooper et al., PLoS One, 2015; Gall et al., J. Heart and Lung Transplantation, 2017

4. Olsson et al., Eur Respir. J., 2021; Alhamad et al., J Clin Med., 2020

5. Humbert et al., Eur Respir J., 2023; Dhont et al., ERJ Open Res., 2022

# PH-ILD is Even More Prevalent than PAH (~\$6BN Market) but Has Only One Approved Therapy in US and None Ex-US

	<b>PAH</b> <i>Group 1</i> <i>Idiopathic PAH or Connective-Tissue Disease Associated PAH</i>	<b>PH-ILD</b> <i>Group 3</i> <i>PH associated with interstitial lung disease</i>
<b>US &amp; EU Patient Population</b>	70 – 100k patients <sup>1</sup> 	Up to ~200k patients <sup>2</sup> 
<b>Competitive Landscape</b>	15+ approved therapies, across five drug classes 	<b>High unmet need</b> Only 1 approval in PH-ILD (US only, among major markets) 
<b>Commercial Validation<sup>4</sup></b>	Generated multiple blockbuster products 	Only approved therapy approaching \$1BN in annual US PH-ILD sales just ~3 years into launch 
<b>Market Size</b>	~\$6BN <sup>3</sup>	<b>Potentially &gt;\$6BN<sup>4</sup></b>

# Moslicigat has an Ideal Target Product Profile, with Potential to Differentiate Across All Three Key Domains – Efficacy, Convenience and Safety/Tolerability

## Efficacy

### “Big Gun”

- Group 1 PH experience shows that the ability to reduce PVR is a predictor of success
- Tyvaso Phase 3 INCREASE study in PH-ILD confirms this principle translates to Group 3 PH for inhaled therapies<sup>1</sup>
- Moslicigat is able to generate greater PVR reductions than any product to date in a single-dose setting (exceeding what many can do even with repeat dosing)

## Convenience

### One Puff per Day

- A single dose of moslicigat is able to drive sustained cGMP elevation through 24 hours, while every other approved inhaled product requires between one and twelve breaths given 4x per day
- Moslicigat is delivered via DPI, preferable to cumbersome nebulizers

## Safety / Tolerability

### Safe and Well Tolerated

- Inhaled prostacyclins carry class AEs that preclude many patients from reaching maximally effective doses and lead to significant rates of discontinuation
- sGC modulation has been shown to be safe and well tolerated when delivered as an inhaled therapy (minimizing systemic exposure)

**Moslicigat well-positioned for front-line use in PH-ILD;  
Tyvaso’s consensus ~\$1.5-\$2BN peak sales for PH-ILD sets floor for opportunity**

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Robust Phase 1 Program Demonstrates that Mosliciguat is a Potent sGC Activator with a Favorable Safety Profile

Given to 170 healthy volunteers and patients with PH<sup>1</sup>

Trial (Population)	N <sup>1</sup>	Duration	Findings
<b>SAD</b> (HVs)	62	Single dose	<ul style="list-style-type: none"> <li>Inhaled dose range of 0.06-4.0 mg well tolerated</li> <li>Dose-dependent increase in cGMP</li> </ul>
<b>MAD</b> (HVs)	27	7-day	<ul style="list-style-type: none"> <li>Inhaled dose range of 0.48-2.0 mg well tolerated</li> <li>Accumulation and dose-dependent increases in cGMP confirms <b>effective once-daily dosing</b></li> </ul>
<b>Bioavailability</b> (HVs)	26	Single dose	<ul style="list-style-type: none"> <li><b>Determined inhaled bioavailability</b></li> <li>Inhaled, oral and intravenous dosing well tolerated</li> </ul>
<b>MAD</b> (HVs)	17	14-day	<ul style="list-style-type: none"> <li>Well tolerated over 14 days</li> <li>Steady state of cGMP production <b>achieved in &lt;14 days</b></li> </ul>
<b>ATMOS</b> (Group 1 / 4 PH)	38	Single dose	<ul style="list-style-type: none"> <li>Data presented at ERS</li> <li>Primary endpoint: PVR reduction</li> </ul>
<b>Total</b>	<b>170</b>		

# sGC Modulation is Ideally Suited for Disease Modification in Pulmonary Hypertension

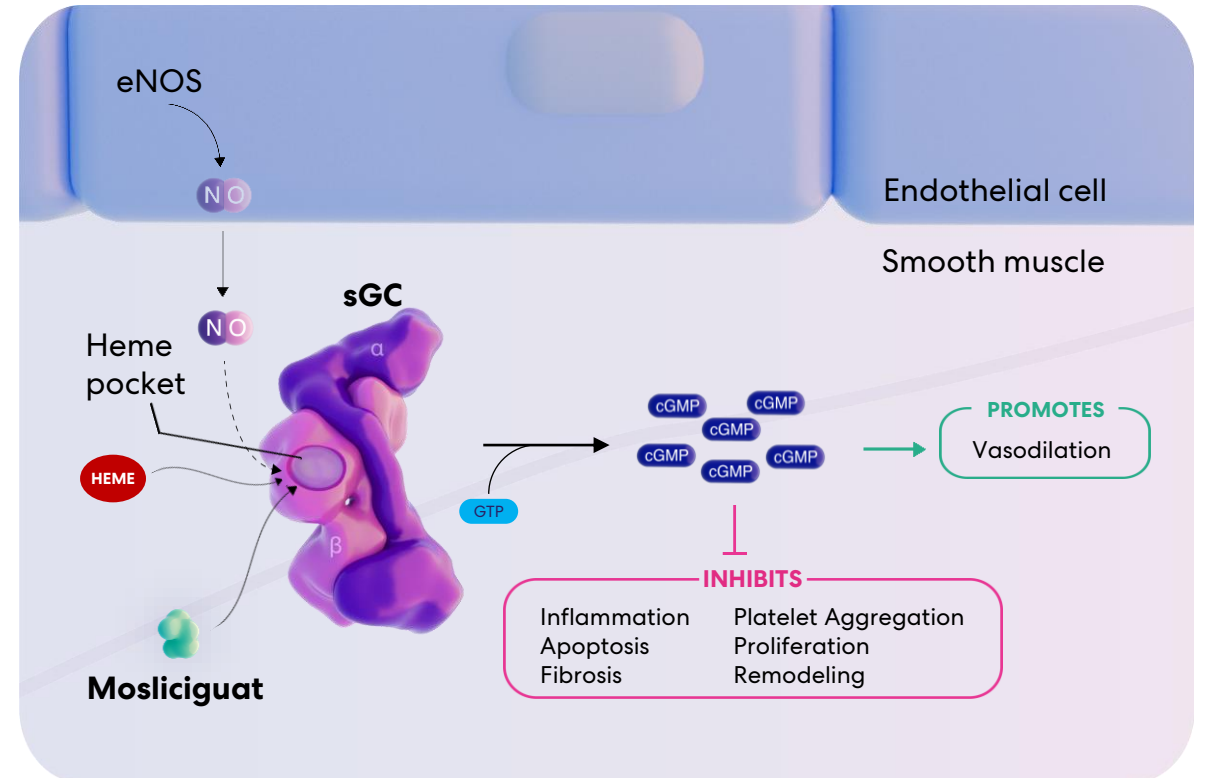
sGC is a key enzyme in the nitric oxide (NO) and cyclic guanosine monophosphate (cGMP) signaling pathway that helps maintain vascular homeostasis

sGC catalyzes conversion of GTP to cGMP, a key messenger molecule responsible for a wide variety of desirable outcomes<sup>1</sup>

Both reduced heme and NO are required for maximal sGC activity

PH and lung disease are often associated with high oxidative stress, leading to impaired sGC activity and insufficient levels of cGMP

sGC modulation restores impaired sGC activity and recovers cGMP levels



# Mosliciguat, an sGC Activator, Should Outperform an sGC Stimulator in the Oxidative Environment of PH-ILD



Broad applicability makes mosliciguat the “go to” sGC modulator

# Approved PH Therapies Have Consistently Generated ~20-30% PVR Reductions, Yielding Improved Clinical Outcomes and Numerous Blockbuster Products

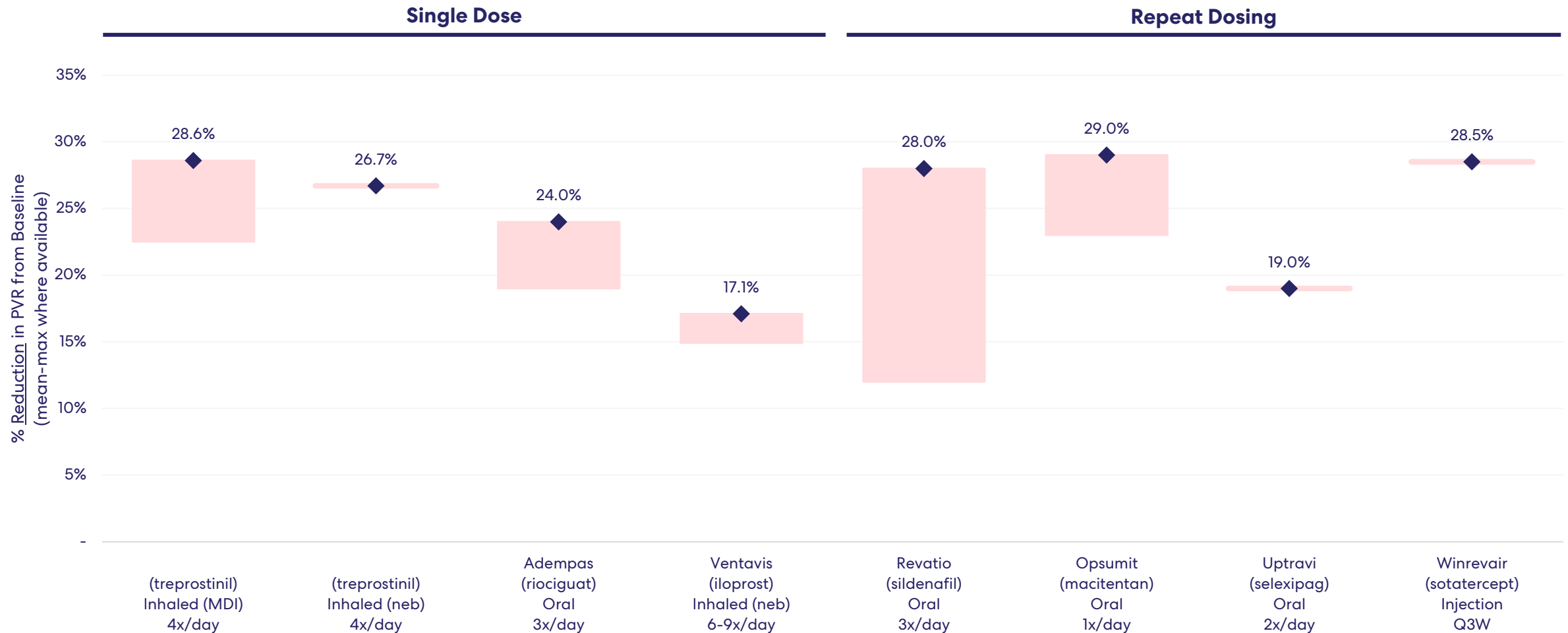


Figure represents a cross-study comparison and not a head-to-head study. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Moslicigat has Shown Among the Highest PVR Reductions Ever Seen in the Single or Repeat Dose Setting

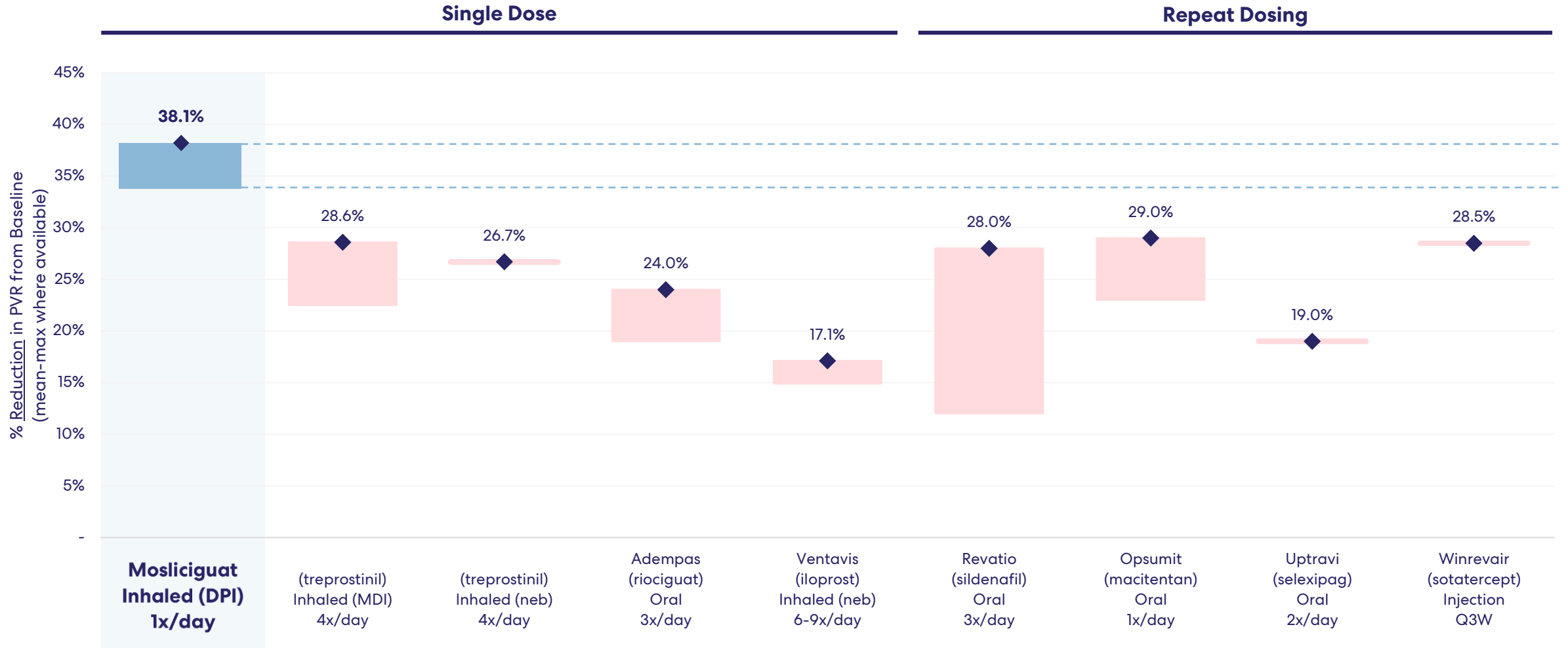
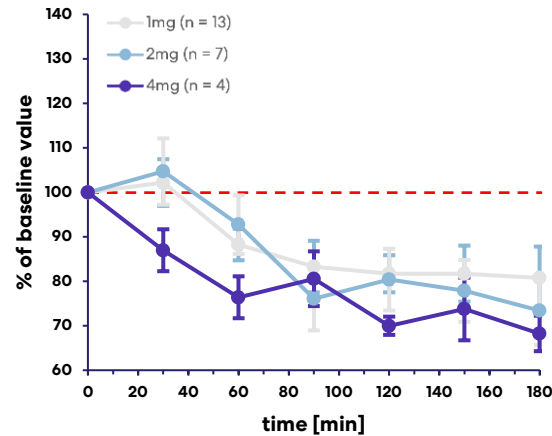


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# Mosliciguat Pairs Best-In-Category PVR Reductions with a Superior Dosing Profile and Formulation

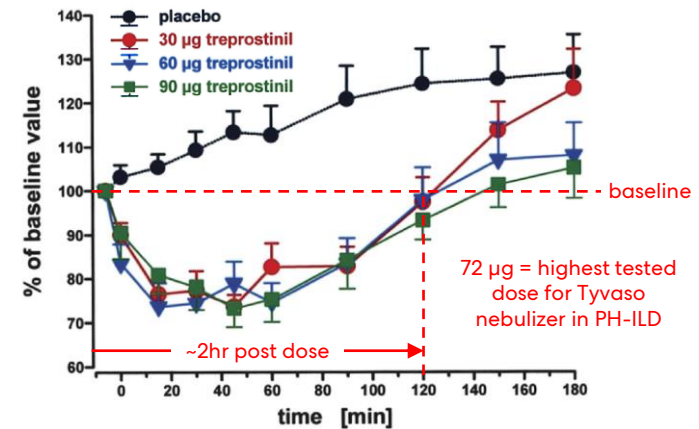
Single dose of mosliciguat has shown...



- >30% PVR reductions continue to deepen as of last time point measured (3 hours post-dose)
- C<sub>max</sub> at ~2-2.5 hours with extended half-life in blood of ~40+hr
- cGMP levels peak 8 hours post-dose, are sustained through 24 hours and rise with repeat dosing

Highly convenient  
“One Puff per Day” dosing

Single dose of inhaled treprostinil has shown...



- A short half-life, leading to small window of effect: PVR back to baseline in as little as 2 hours<sup>1</sup>
- 6MWT effects are reduced at trough exposures<sup>2</sup>

Tyvaso has 4x daily dosing, with majority of day and entire night still spent with suboptimal PVR reductions

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Safety Data Indicate All Dose Levels of Mosliciguat Were Well-Tolerated in Both Healthy Volunteers and Patients with PH

## Mosliciguat SAD/MAD and ATMOS Phase 1b Data Show Clean Safety and Tolerability Profile







- Majority of treatment emergent adverse events were mild
- Continuous dosing in healthy volunteers (HV) for 7-14 days did not reveal relevant additional events compared to single-dose experience in HV and PH patients
- No clinically significant changes to blood pressure or heart rate suggest successful minimization of systemic side effects
- All doses tolerated as inhaled dry powder without significant cough
- “One Puff per Day” dosing further mitigates risk of cough

## Tolerability Concerns for Inhaled Prostacyclins as a Class

- Inhaled prostacyclin-related AEs include high rates of cough, throat irritation, oropharyngeal pain and headache
- These AEs are likely to occur with any inhaled prostacyclin, regardless of frequency of administration or formulation
- In Tyvaso’s Phase 3 PH-ILD study (INCREASE) with 4x/day nebulizer:<sup>1</sup>
  - ~45% of Tyvaso patients had cough
  - less than half reached the top dose level (72 µg), likely due to poor tolerability
- In the INCREASE OLE, AEs led to 22% of patients discontinuing drug<sup>2</sup>

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Potential for Best-in-Category Profile with Robust Efficacy, Favorable Tolerability and Safety, and a Convenient, One Puff per Day Dosing Regimen

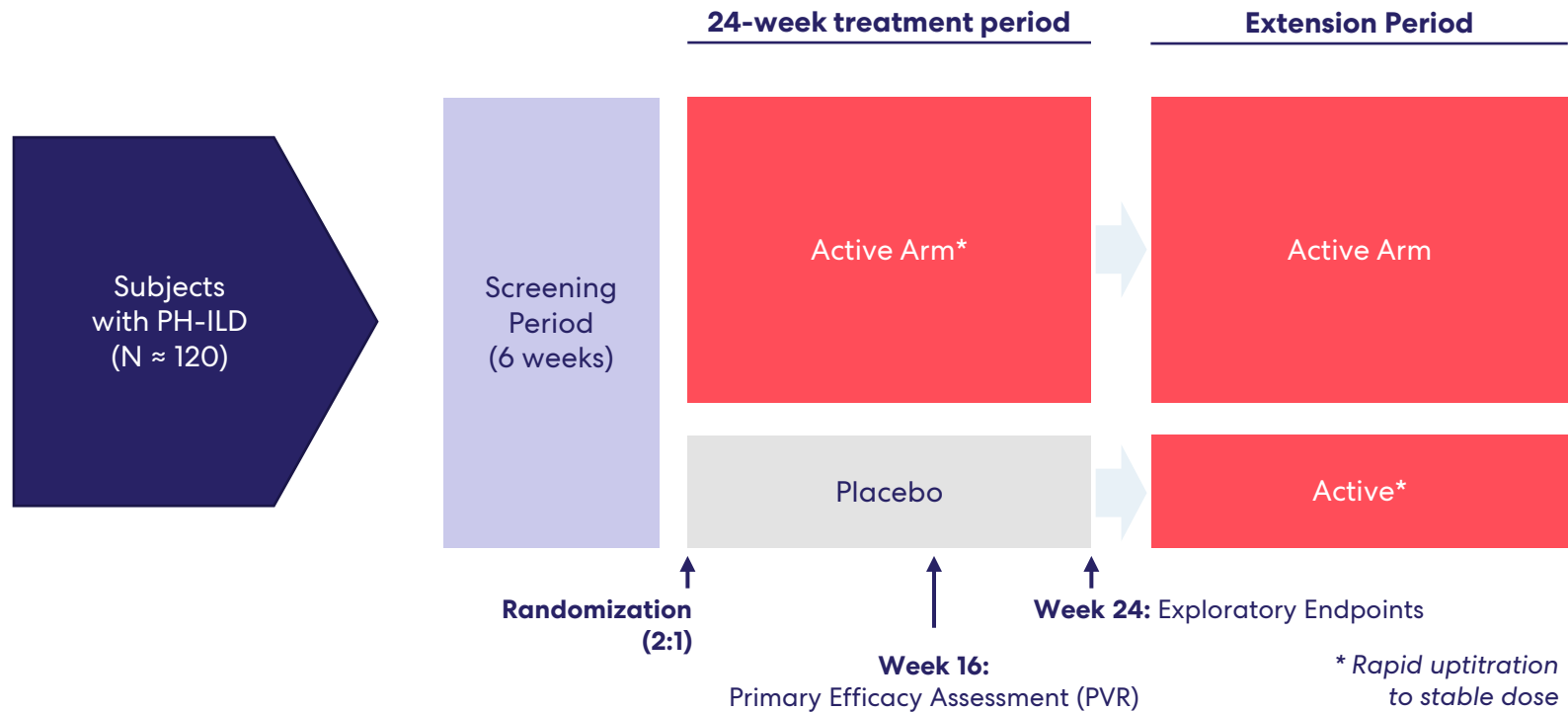
	Moslicigat	Tyvaso + Other Inhaled Prostacyclins <sup>1</sup>	Seralutinib <sup>2</sup>	MK-5475 <sup>3</sup>
<b>Company</b>		  		
<b>Group 3 PH Stage of Development</b>	Phase 2	Marketed or Pending Phase 3	Pending Phase 3	Phase 2 (in PH-COPD only)
<b>MOA</b>	sGC activator	Prostacyclin	PDGFR $\alpha/\beta$ , CSF1R and c-KIT inhibitor	sGC stimulator
<b>Administration</b>	Inhaled	Inhaled	Inhaled	Inhaled
<b>&gt;30% PVR Reductions with Once Daily Dosing</b>	✓	✗	✗	✗
<b># Inhalations / Day</b>	1	Up to 48	Up to 12	TBD
<b>Half-life</b>	~40+ hours	~0.5–9 hours	~3–6 hours	~2–3 hours
<b>Tolerability</b>	✓	✗	⤿	✓

No head to head studies have been conducted. Differences exist between study designs and subject characteristics, and caution should be exercised when comparing data across studies.

# Phase 2 PHocus Study of Mosliciguat to Begin Imminently

Multi-center, global trial in ~120 PH-ILD patients

phocus



## Eligible Patients

Eligible participants diagnosed with PH-ILD

## Inclusion/Exclusion Criteria

- Confirmed ILD (IIP, CHP, ILD-CTD)
- Elevated baseline PVR
- Pre-defined extent of fibrosis and emphysema as measured by CT

## Primary Endpoint

Change from Baseline PVR

## Secondary / Exploratory Endpoints

- Change from baseline 6MWD
- Change from baseline NT-proBNP
- Time-to-clinical-worsening (TTCW) at W24
- QoL

If Phase 2 is positive, we believe a single registrational study will be sufficient for approval

# Immunovant: Graves' Disease Program Update

# Multiple Market-Sizing Analyses Confirm High Unmet Need in Graves' Disease with at Least 25-30% of Patients Relapsed, Uncontrolled, or Intolerant to ATDs

1

Conservative Inovalon claims analysis yields ~880K prevalent Graves' Disease patients

2

Conservative Inovalon claims analysis yields ~65K incident Graves' Disease patients

3

Deep dive endocrinologist survey of 140 healthcare providers treating Graves' Disease patients indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

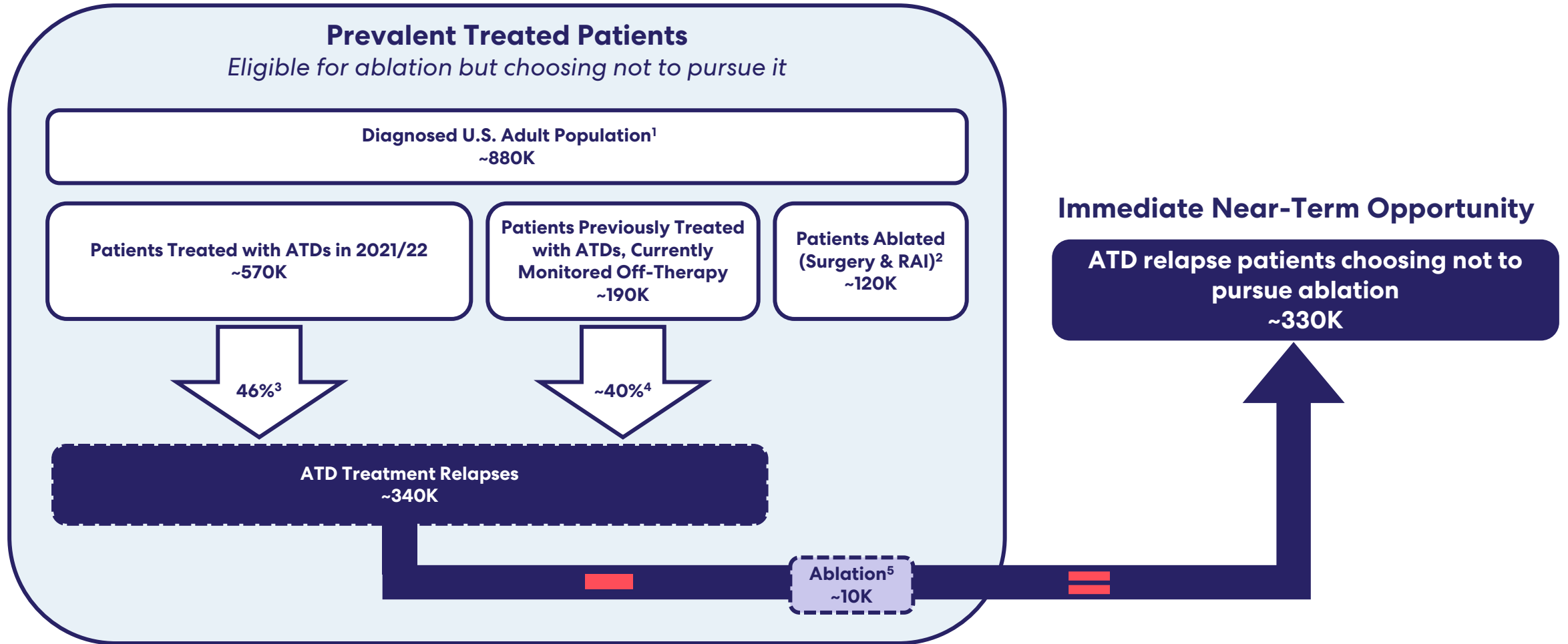
4

Real-world chart audit of 1,120 Graves' Disease patients treated by surveyed endocrinologists indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

5

Patient survey of 100 diagnosed Graves' Disease patients indicates ~25-30% of patients are relapsed, uncontrolled, or intolerant to ATDs

# Real World Claims Analysis Indicates a Substantial Untapped Opportunity in the Prevalent Treated Graves' Disease Market



1. Roivant Claims Analysis – 2022 prevalent patient population based on a two-year lookback for diagnosis  
 2. Of the 121K patients ablated, 77.4K were ablated prior to 2021 and 43.4K were ablated in 2021/2022  
 3. Azizi et al. (2019): Note, the relapse rate was calculated as a weighted average considering relapse rate in patients on ATDs <18months is 53% compared to patients on ATDs >18months is 15%. Of the 571K patients treated with ATDs, 467K are on ATDs <18months and 104K are on ATDs >18months. Rates have been applied proportionally  
 4. Bandai et al. (2019): Of the 188K patients previously treated with ATDs and currently monitored off-therapy, ~40% experience relapse, which is 75K  
 5. Grove-Laugesen et al. (2023): 3.4% of ATD relapse patients will pursue ablation. 3.4% applied to the 338K ATD treatment relapse patients is 11K

# Proof of Concept Achieved in Graves' Disease, Positioning IMVT-1402 to Potentially be Best-in-Class and First-in-Class



**>75% Response Rate in Patients Uncontrolled on Anti-Thyroid Drugs (ATDs):** T3 and T4 rapidly normalized by Week 12 without an increase in ATDs in 76% of patients



**>50% of Patients are ATD-Free Responders:** 56% of patients not only achieved normal T3 and T4 levels but also ceased ATD therapy entirely by 12 weeks



**Lower is Better:** Deeper IgG reductions drove meaningfully higher response rates, positioning IMVT-1402 to potentially be best-in-class



**High Unmet Need Yields Attractive Commercial Opportunity:** 25-30% of Graves' Disease patients per year are uncontrolled on / intolerant to ATDs with no pharmacologic options

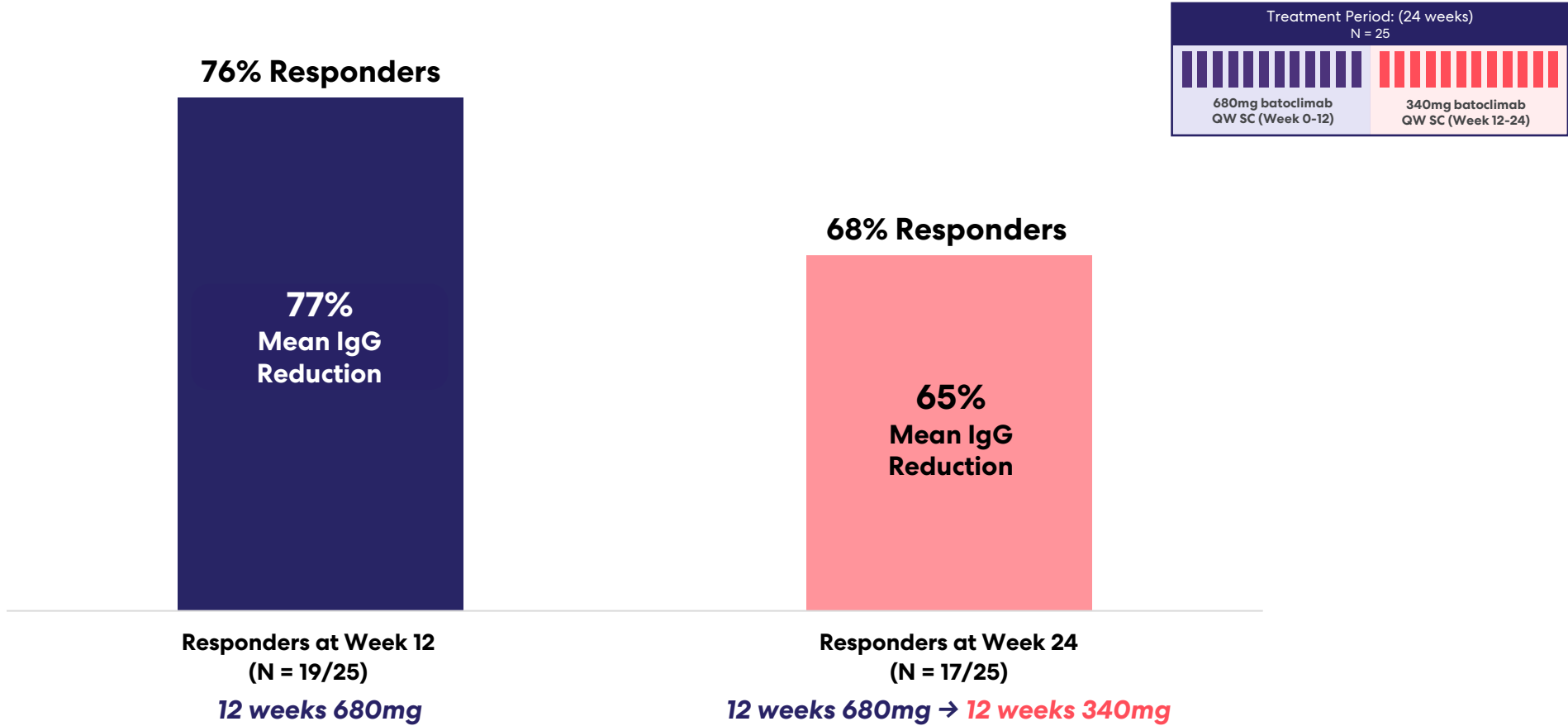


**IMVT-1402 IND Cleared:** Received FDA greenlight, enabling straight to pivotal transition



# Batoclimab Demonstrated Potentially Transformational Results in ATD- Uncontrolled Patients with Greater Response Driven by Higher IgG Lowering

**% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, without increase in ATD**



# >50% of Patients Receiving High-Dose Batoclimab Not Only Achieved Normal T3 and T4 Levels but Also Ceased ATD Entirely by 12 weeks

% of participants who achieve normal T3 and T4 or have T3 or T4 below LLN, and ceased all ATD medications

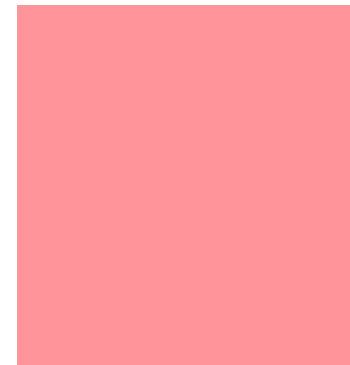
56% ATD-Free Responders



Week 12  
(N = 14/25)

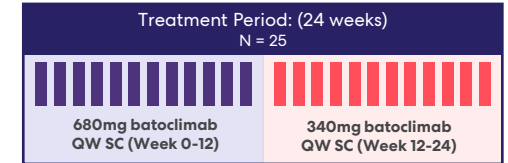
12 weeks 680mg

36% ATD-Free Responders



Week 24  
(N = 9/25)

12 weeks 680mg → 12 weeks 340mg

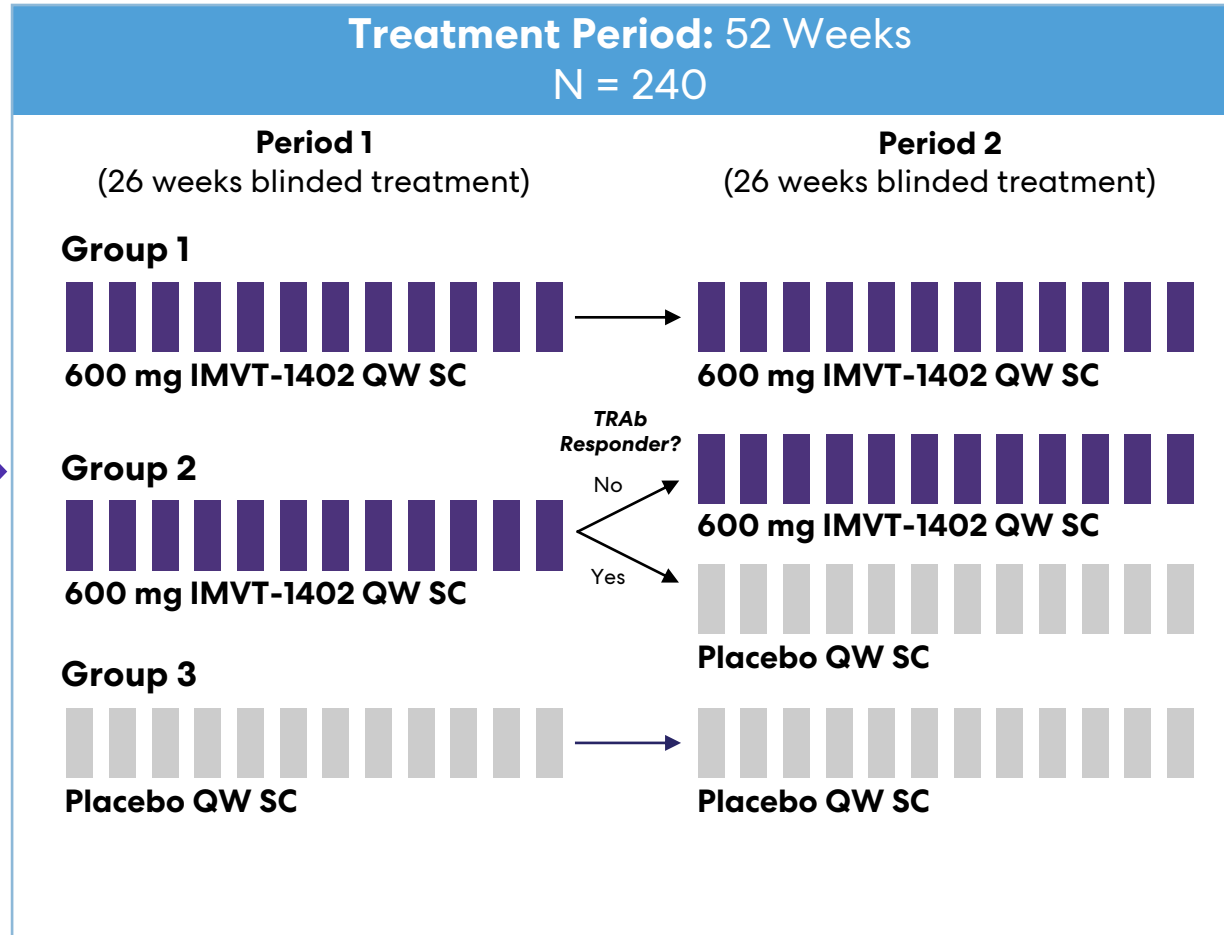


# First Pivotal Trial for IMVT-1402 in Graves' Disease

## Inclusion<sup>1</sup>

- Adults with active Graves' Disease as documented by presence of TSH-R binding autoantibodies
- Subjects on an ATD for  $\geq 12$  weeks before the Screening Visit
- Subjects who are hyperthyroid based on suppressed TSH despite ATD

Randomization (1:1:1)



Off-Treatment Follow-Up (52 Weeks)

**Primary Endpoint:**  
Proportion of participants who become euthyroid<sup>2</sup> and stop ATD at week 26

**Key Secondary Endpoint:**  
Proportion of participants who become euthyroid<sup>2</sup> and stop ATD at week 52

**Design enables study of remission as upside**

ATD titration to lowest effective dose (including 0 mg/day) to maintain euthyroidism

Thank you.

roivant

