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Seralutinib Program Update:  
PROSERA Phase 3 Design and Interim TORREY OLE Results

*July 25, 2023*

# Forward Looking Statements

*This presentation contains forward-looking 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, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions.*

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# Presenters for Today's Call

## Gossamer Bio

<b>Faheem Hasnain</b>	Co-Founder, Chairman, & Chief Executive Officer
<b>Richard Aranda, MD</b>	Chief Medical Officer
<b>Robert Roscigno, PhD</b>	VP, Clinical Development
<b>Caryn Peterson</b>	EVP, Regulatory Affairs
<b>John Kempen</b>	VP, Head of Global Clinical Operations
<b>Bryan Giraudo</b>	COO & CFO

## Guest Speakers

**Dr. Ray Benza**  
Icahn School of Medicine at Mount Sinai

**Dr. Ardi Ghofrani**  
University of Giessen

**Dr. Jim White**  
University of Rochester

# TORREY Study Phase 2 Topline Results

- **Met Primary Endpoint:** Statistically significant reduction in PVR in heavily-treated study population
- **Consistent, favorable PVR benefit seen in all pre-specified sub-groups** in favor of seralutinib with enhanced effects in patients with more severe disease at baseline<sup>§</sup>

Overall Study Population			Functional Class III			REVEAL 2.0 Risk Score ≥ 6		
PVR	NT-proBNP	6MWD	PVR	NT-proBNP	6MWD	PVR	NT-proBNP	6MWD
-14%*	-408 ng/L*	+6.5m	-21%*	-527 ng/L*	+37.3m*	-23%*	-732 ng/L*	+21.9m
p = 0.0310	p = 0.0012	p = 0.5972	p = 0.0427	p = 0.0055	p = 0.0476	p = 0.0134	p = 0.0002	p = 0.2482

**Primary Endpoint**

- Consistently favorable results for hemodynamic and ECHO endpoints
- **Well tolerated**, avoiding side effect profile associated with systemic imatinib in PAH

\* = p-value ≤ 0.05. All p-values in this presentation are nominal, aside from primary endpoint (overall study population delta in PVR).

§ At baseline, as determined by Functional Class and REVEAL 2.0 Risk Score (pre-specified subgroups).

Functional Class II patients showed a placebo adjusted PVR improvement of -66.9 dynes\*sec\*cm<sup>-5</sup> (p = 0.2601) from baseline.

# Selected Baseline Disease Characteristics

(ITT Population)

Characteristic	Placebo (N=42)	Seralutinib (N=44)	Total (N=86)
Number of PAH background therapies – n (%)			
1	2 (4.8)	1 (2.3)	3 (3.5)
2	16 (38.1)	18 (40.9)	34 (39.5)
3	24 (57.1)	25 (56.8)	49 (57.0)
WHO FC – n (%)			
Class II	20 (47.6)	<b>30 (68.2)</b>	50 (58.1)
Class III	<b>22 (52.4)</b>	14 (31.8)	36 (41.9)
PVR (dyne*s/cm <sup>5</sup> ) – mean (SD)	661.3 (164.91)	675.8 (240.35)	<b>668.7 (205.90)</b>
6MWD (m) – mean (SD)	407.1 (107.02)	408.6 (75.11)	<b>407.9 (91.54)</b>
NT-proBNP (ng/L) – mean (SD)	645.6 (1158.75)	611.0 (714.58)	<b>628.3 (956.83)</b>

Heavily pre-treated patient population

Hit Primary Endpoint Despite FC Imbalance in Drug & Pbo Arms

Mildest baseline PAH disease to see treatment effect\*

STELLAR Trial Phase 3 NT-proBNP mean baseline was 1,121.1ng/L; PVR was 763.7 dyne\*s/cm<sup>5</sup> (1)

1) Source: <https://doi.org/10.1056/NEJMoa2213558>.

\*As determined by baseline PVR & 6MWD, we believe that TORREY enrolled the most well-controlled PAH patient trial population to meet its primary efficacy endpoint. 6MWD = six-minute walk distance; FC = Functional Class; NT-proBNP = N-terminal pro B-type natriuretic peptide; PVR = pulmonary vascular resistance; WHO = World Health Organization; ITT = intention-to-treat; SD = standard deviation; Pbo = placebo.

# Today's Agenda

## **I. PROSERA Phase 3 Overview**

- *Richard Aranda, MD, Ray Benza, MD*

## **II. Interim TORREY Phase 2 OLE Extension Results**

- *Rob Roscigno, PhD, Ardi Ghofrani, MD*

## **III. Future Treatment Paradigm in PAH**

- *Faheem Hasnain, Jim White, MD, PhD*

## **Question and Answer**

- *Gossamer Management, Dr. Ray Benza, Dr. Ardi Ghofrani and Dr. Jim White*

# I. PROSERA

## Phase 3 Overview

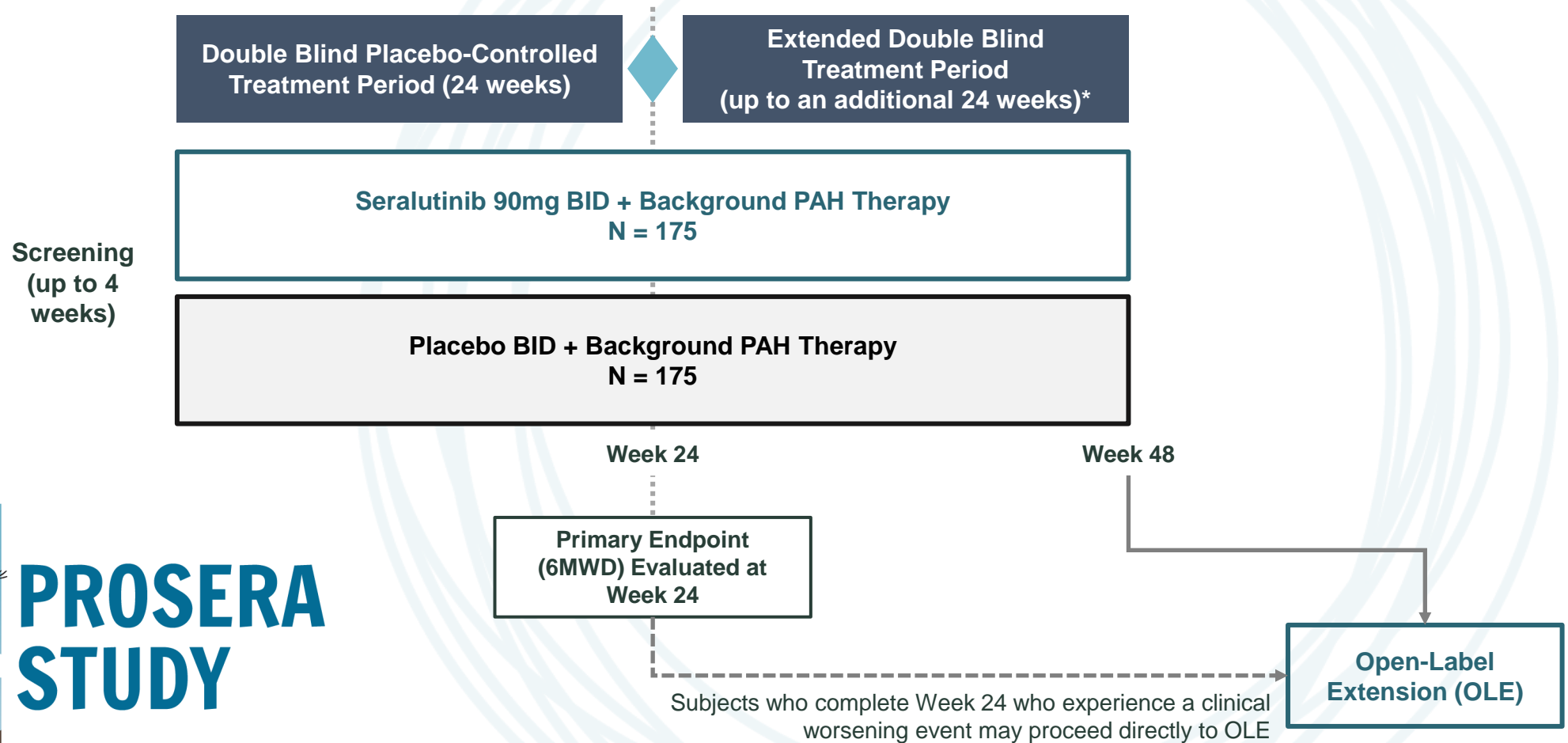


# Regulatory Feedback

- **FDA & EMA - Alignment on the following key design elements of Phase 3 protocol:**
  - **One Dose:** Single dose of seralutinib (90 mg BID); 2-arm study, with ~175 patients per arm
  - **Enriched Population:** Eligibility criteria for a target PAH population based on prespecified subgroup in TORREY with more severe disease and/or who are at higher risk of disease progression, defined by risk score assessment, functional class, PVR and exercise capacity at baseline
  - **Primary Endpoint:** 6MWD at Week 24
- **Additional Comments:**
  - FDA recommended consideration of a Phase 2 study to evaluate disease remodeling (withdrawal)
  - EMA recommended TTCW as key secondary
  - No safety concerns raised



# PROSERA Phase 3 Study Design Schema



**PROSERA  
STUDY**

\*Patients to remain blinded until week 48, until the last patient completes 24-week primary endpoint, after which time the study will be unblinded.  
BID = twice daily dosing; 6MWD = six-minute walk distance.

# PROSERA Study Overview

<b>Design</b>	<ul style="list-style-type: none"><li>• Randomized, double-blind, placebo-controlled, parallel group</li><li>• Up to 48-week double-blinded treatment period; primary endpoint assessed at Week 24</li><li>• Open-label extension option under separate protocol</li></ul>
<b>Primary Endpoint</b>	<ul style="list-style-type: none"><li>• Change in 6MWD at Week 24 from Baseline</li></ul>
<b>Key Secondary Endpoints</b>	<ul style="list-style-type: none"><li>• Time from 1<sup>st</sup> dose to 1<sup>st</sup> event of clinical worsening (TTCW)</li><li>• Proportion of subjects who achieve all components of a composite endpoint of clinical improvement at Week 24 in the absence of clinical worsening:<ul style="list-style-type: none"><li>– Decrease in WHO FC or maintenance of WHO FC II</li><li>– Decrease in NT-proBNP <math>\geq</math> 30% or maintenance at <math>&lt;</math>300 ng/L</li><li>– Increase in 6MWD <math>\geq</math> 10% or <math>\geq</math> 30 m</li></ul></li><li>• Change vs. Baseline in NT-proBNP at Week 24</li><li>• Proportion of subjects with <math>\geq</math> 1 point decrease in REVEAL Lite 2 Risk Score vs. Baseline at Week 24</li></ul>
<b>Stratification at Randomization</b>	<ul style="list-style-type: none"><li>• WHO FC at screening: II vs III</li><li>• Receiving parenteral prostacyclin therapy at Screening (yes vs. no)</li><li>• CTD-APAH (yes vs. no)</li><li>• Participation in CT sub-study (yes vs. no)</li></ul>

# PROSERA Phase 3 Study Population



## PROSERA STUDY

### Key Inclusion Criteria

- Adults  $\geq 18$  and  $\leq 75$  years old
- WHO Group 1 PAH
- WHO Functional Class II or III
- $PVR \geq 400 \text{ dyne}\cdot\text{s}/\text{cm}^5$
- Baseline 6MWD 150 - 450m\*
- Either REVEAL Lite 2 Risk Score  $\geq 5$   
or NT-proBNP  $\geq 300 \text{ ng/L}^*$
- Stable treatment with at least one SOC background therapy

\* Key enrichment criteria.

WHO = World Health Organization; PVR = pulmonary vascular resistance; 6MWD = six-minute walk distance; NT-proBNP = N-terminal pro B-type natriuretic peptide; SOC = standard of care

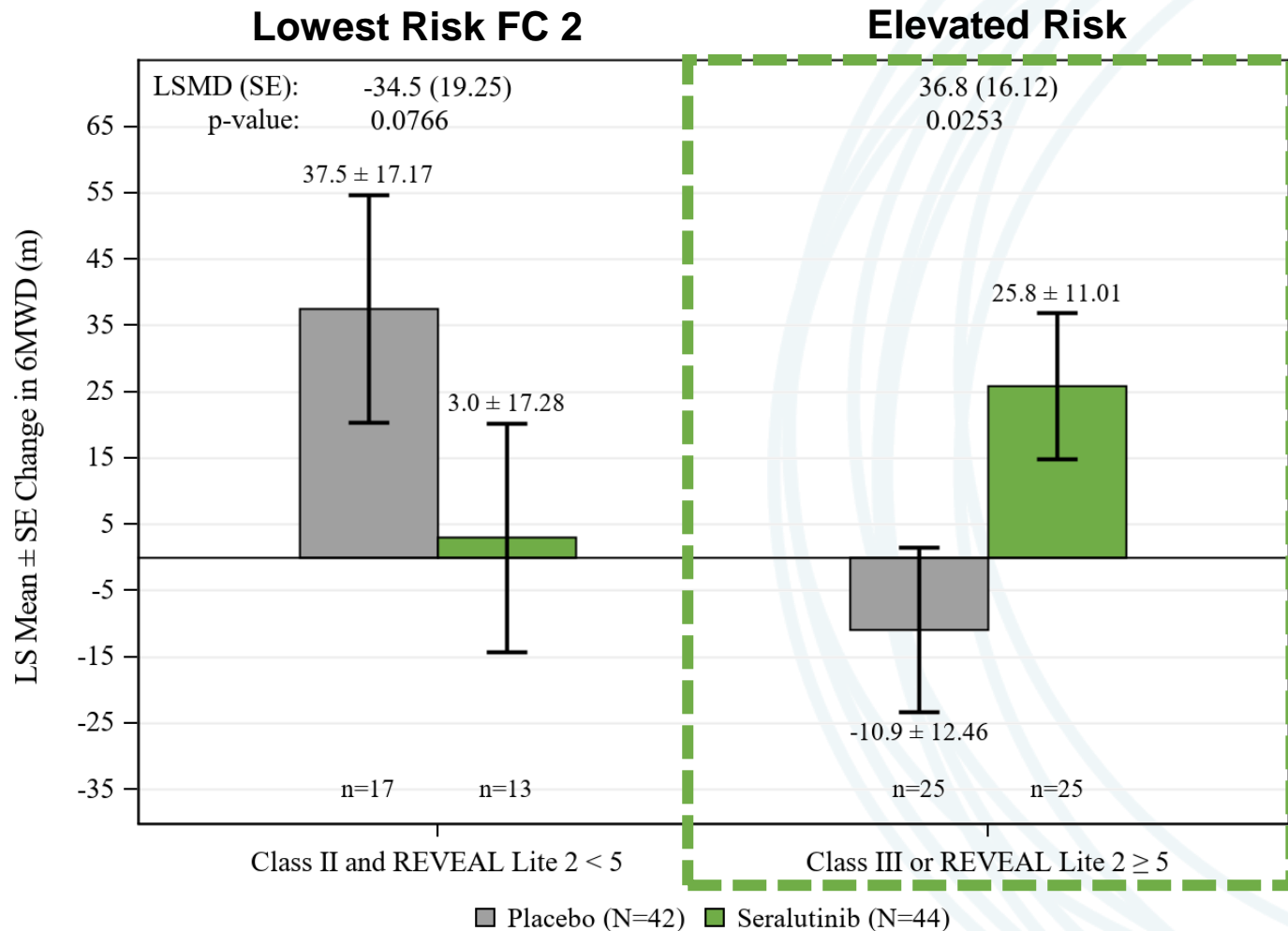
# What is REVEAL Lite 2?

- Abridged version of REVEAL 2.0 risk assessment
  - Validated to approximate discriminatory features of REVEAL 2.0 Score
  - Built for ease of use in daily clinical practice
- Six noninvasive and modifiable variables
  - No need for invasive right heart catheterization (RHC)
  - REVEAL 2.0 Score incorporates 11 measures and requires an RHC

REVEAL Lite 2 Risk Calculator				
BNP (ng/L)	<50 -2	50 to <200 0	200 to <800 1	≥800 2
OR				
NT-proBNP (ng/L)	<300 -2	300 to <1100 0	≥1100 2	
6MWD	≥440 -2	320 to >440 -1	<320 to 165 0	<165 1
WHO FC	I -1	II 0	III 1	IV 2
Systolic BP (mmHg)		≥110 0	<110 1	
Heart Rate (BPM)		≤96 0	>96 1	
eGFR<60mL/min/1.73m <sup>2</sup> or renal insufficiency		No 0	Yes 1	
	<b>Sum of above + 6</b>			
	Low Risk	Intermediate Risk	High Risk	
Risk Score	≤5	6-7	≥8	

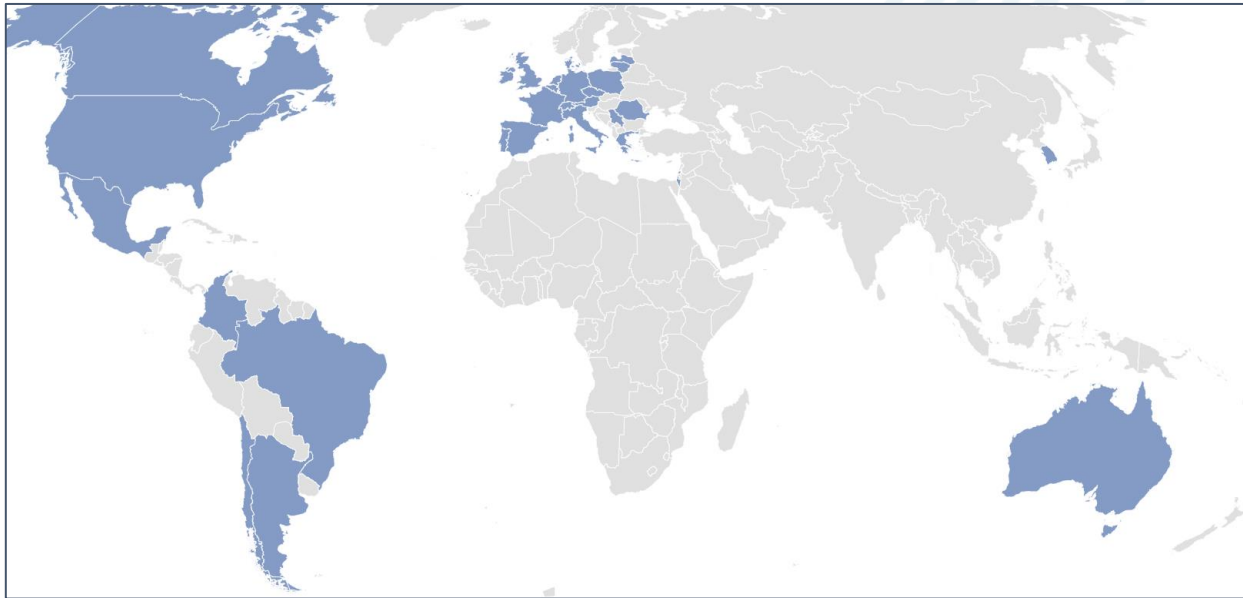
# Further Validation of REVEAL Lite 2 Enrichment for Phase 3

## TORREY Week 24 $\Delta$ 6MWD with REVEAL Lite 2 Score Incorporated



- Right side consists of patients who are
  - Class II (n=15)
  - Class III (n=35)
- Treatment effect in this population used as a basis for powering phase 3 with a conservative adjustment ( $\Delta = 30$  m, SD=70,  $\alpha=0.025$ )
  - >95% power with 175 patient / arm

# Broad Global Footprint with Trusted Sites and Clinical Partners



**US and Canada: 50+ Sites**

**Latin America: ~25 Sites**

**Europe: 75+ Sites**

**Asia Pacific: 10+ Sites**

Country with Study Site 

- Broad global footprint planned: > 160 sites across ~30 countries
- Experienced global Gossamer team to support sites, educate, and drive enrollment
- **Strong CRO partner (PPD) with deep experience in PAH**
- Enrollment target: 18 months

# Primed for Phase 3

- **Regulatory feedback supportive of single registrational study evaluating 90mg BID dose**
  - FDA and EMA aligned on all key components of study; protocol finalized
- **Phase 3 trial incorporating learnings from TORREY targeted to initiate in August**
  - Use of REVEAL Lite and NT-proBNP as enrichment factors for 6MWD success
  - **Use of PPD as CRO helps to de-risk execution of enrollment and 6MWT conduct**

# II. Interim TORREY OLE Results

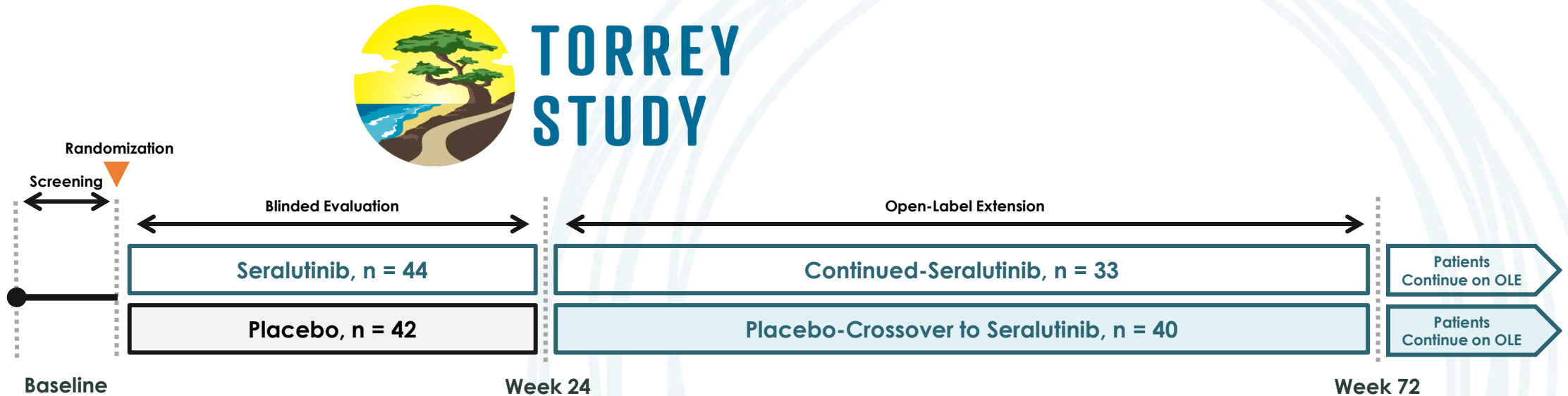
*Data available to date –  
Subject to change –  
Study is ongoing*

*Data as of June 23, 2023.*





# TORREY Open-Label Extension Interim Update



- Of 80 TORREY completers (38 seralutinib arm, 42 placebo arm), 73 (91.3%) elected to rollover into the open-label extension
- PVR measured via right heart catheterization at Baseline, Week 24, and Week 72 (approximately 1 year into OLE)
- **As of interim data cutoff date, Week 72 PVR data available for 30 patients**
  - **16 continued-seralutinib, 14 placebo-crossover**

# Seralutinib Profile Emerging From OLE

- ✓ Seralutinib treatment leads to hemodynamic improvement in ~60-70% of patients
  - ✓ Almost all patients who have short-term benefit (at 6 months) continue to improve with long-term treatment
- ✓ The continued improvement in PVR, along with the ECHO and FRI data gathered in TORREY, is supportive of a reverse remodeling mechanism of action
- ✓ Safety and tolerability remain relatively benign, with no safety signals emerging or worsening with long-term use
- ✓ Drug delivery via DPI twice daily well-accepted and easy to incorporate into a patient's daily routine
- **Seralutinib has the potential to be used prior to more invasive / inconveniently delivered therapies and / or those with challenging safety / tolerability profiles (e.g., prostacyclins)**

# Interim Analysis Shows Deepening PVR Improvement in Continued-Seralutinib Group

## Baseline

Median Baseline PVR:

**541**  
dyne\*s/cm<sup>5</sup>

- 10 WHO Functional Class II, 6 WHO Functional Class III
- 50% on dual background therapy, 50% on triple background therapy

*End of TORREY*

## Week 24

Median Change in PVR  
vs. Baseline:

 **-70.5**  
dyne\*s/cm<sup>5</sup>

- 11 / 16 had improvement in PVR
  - Mean improvement of PVR responders at week 24 = 24%

*OLE PVR Data Point*

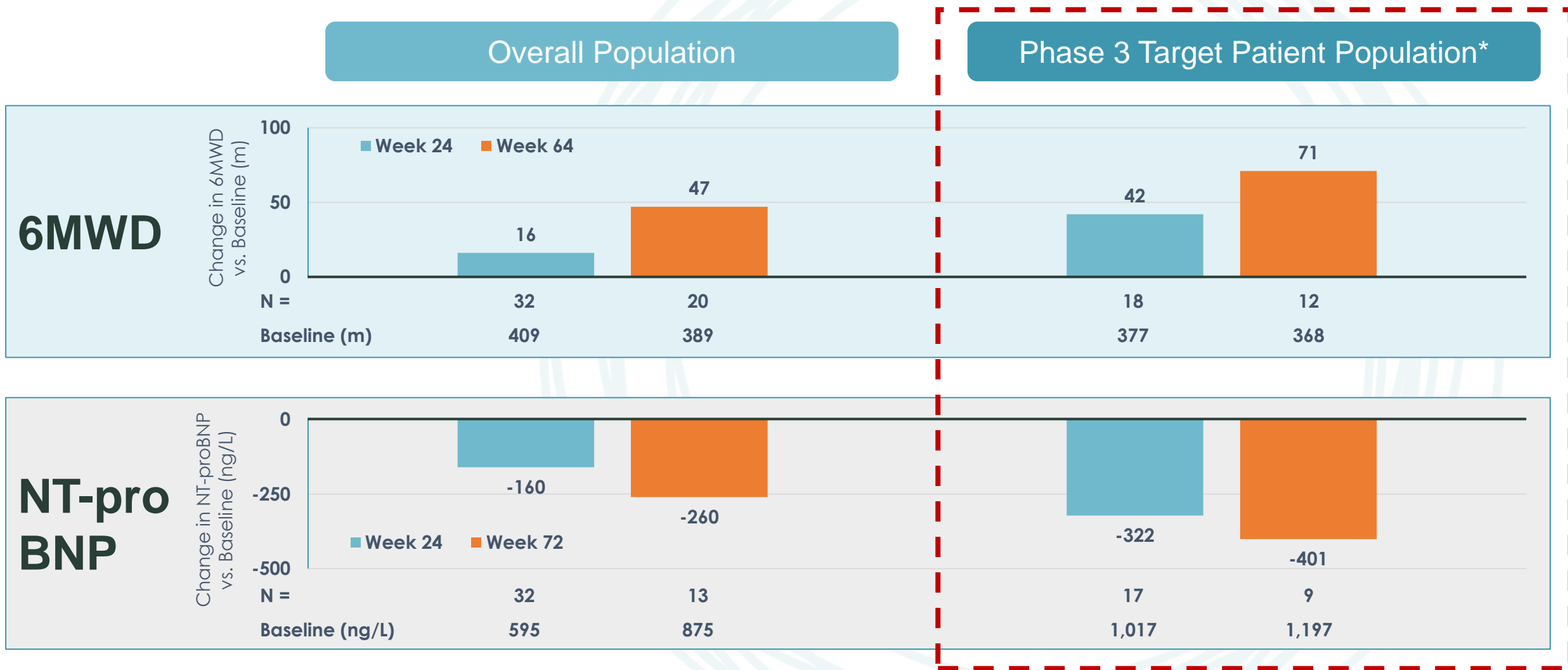
## Week 72

Median Change in PVR  
vs. Baseline:

 **-142.5**  
dyne\*s/cm<sup>5</sup>

- All 11 initial responders maintained PVR below baseline
- 9 / 11 continued to improve
  - Mean improvement of 9 PVR dual responders = 39%
  - 3 patients reached a PVR below 200 dyne\*s/cm<sup>5</sup>

# Further Improvements Seen in 6MWD and NT-proBNP for Phase 3 Target Population in Continued-Seralutinib Group

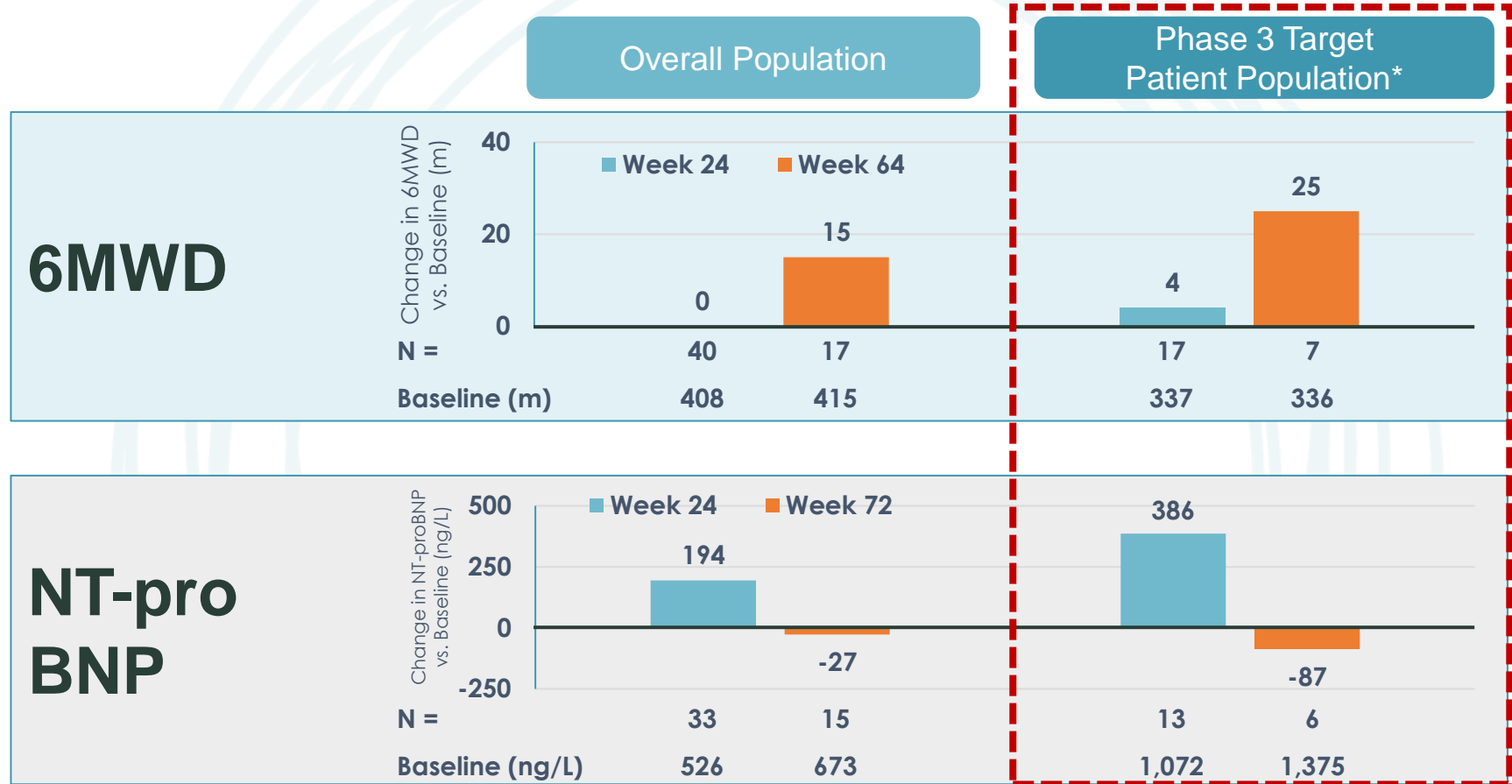


\* REVEAL Lite 2 Risk Score  $\geq 5$  at TORREY baseline.  
6MWD = six-minute walk distance; NT-proBNP = N-terminal pro B-type natriuretic peptide.

# Encouraging Early Trends Observed in Placebo-Crossover Group

## PVR at Week 72

- 7 / 14 patients had improvement in PVR after beginning seralutinib treatment in OLE
- 11 / 14 patients had improved PVR vs. baseline



- 6MWD improvement in OLE driven by Phase 3 target population
- NT-proBNP increase while on placebo during TORREY reversed after patients started on seralutinib treatment

\* REVEAL Lite 2 Risk Score  $\geq 5$  at TORREY baseline.  
PVR = pulmonary vascular resistance; OLE = open-label extension; 6MWD = six-minute walk distance; NT-proBNP = N-terminal pro B-type natriuretic peptide.

# TORREY OLE Safety To Date

- Safety results consistent with controlled period – serralutinib generally well tolerated with no new safety concerns
  - Results support chronic treatment in PAH patients
- Reports of cough diminish as patients get used to DPI
- Vast majority of patients have reached and maintained 90mg BID dose
  - Limited dose reductions to date
- Limited liver enzyme elevations observed in OLE in similar pattern as TORREY (~5-10%  $\geq 3x$  ULN, similar to placebo rate in TORREY), suggesting potential signal arises early in treatment course and easily monitorable
- Safety tables available in appendix

# Summary of OLE Findings to Date

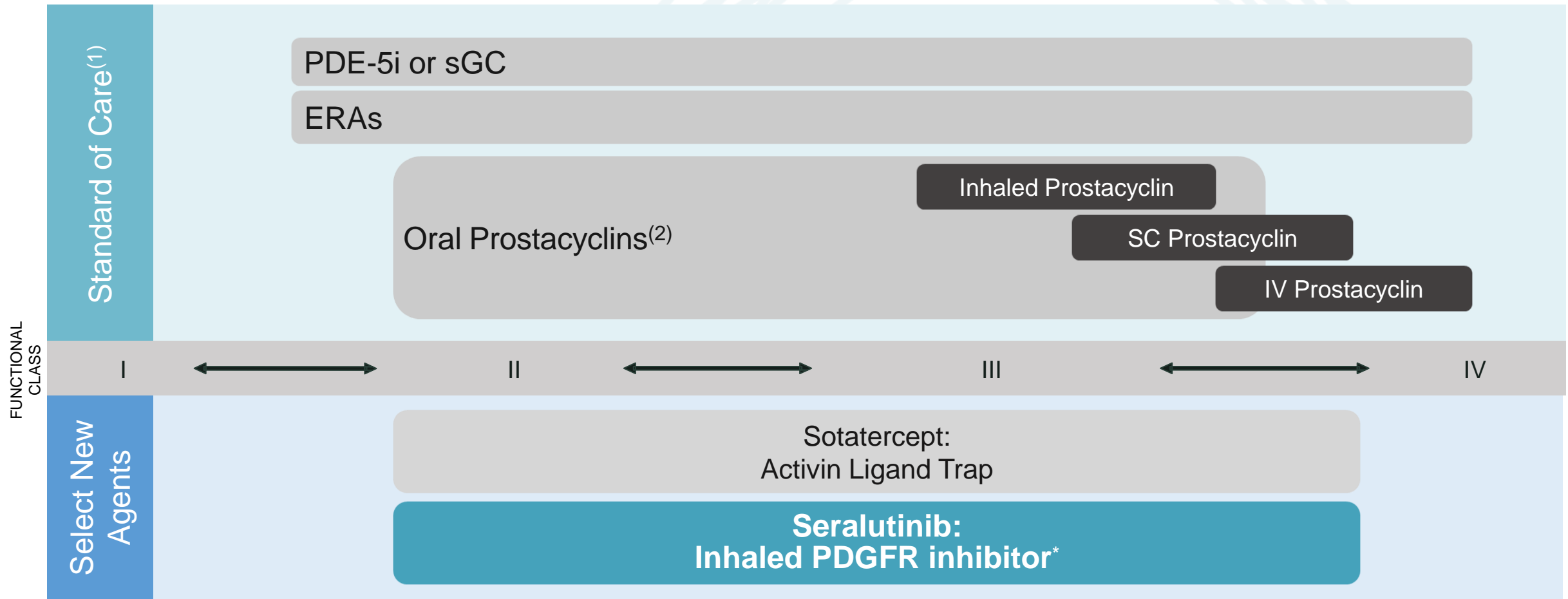
- **Differentiated efficacy and safety profile emerging**
  - Continued improvement in reduction of PVR
    - 30 patients with Week 72 PVR data
    - Early enrollers; milder disease baseline than overall population
  - Continual improvement seen in  $\Delta$ 6MWD &  $\Delta$ NT-proBNP
    - Increased magnitude of effect in Phase 3 target population
  - Attractive safety profile for chronic treatment
- **Convenience, safety / tolerability, and the early signs of an anti-proliferative remodeling effect, present a potentially highly desirable commercial profile**

# III. Future Treatment Paradigm in PAH





# Promising Safety, Tolerability and a Potential Remodeling Mechanism of Action Differentiate Seralutinib from other PAH Therapies



**Seralutinib is being evaluated on-top of background PAH therapy, including prostacyclins**

\*Seralutinib is an inhaled PDGFR, c-KIT and CSF1R inhibitor.

1) Galiè N et al. Eur Respir J 2015; 46(4):903-75;

2) Klinger JR et al. Chest 2019; 155(3): 565-586 (Klinger et al 2019 [CHEST guidelines] removed oral prostacyclin treatments in all FCs).

FC = Functional Class; SC = subcutaneous.

# Q & A



# Appendix – OLE Safety



# Incidence of TEAEs by preferred term: $\geq 5\%$ in total column (Safety Population)

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	Total (N=74)
Number of subjects with a TEAE	38 ( 95.0)	32 ( 94.1)	70 ( 94.6)
Headache	9 ( 22.5)	8 ( 23.5)	17 ( 23.0)
Cough	9 ( 22.5)	7 ( 20.6)	16 ( 21.6)
COVID-19	6 ( 15.0)	7 ( 20.6)	13 ( 17.6)
Diarrhoea	8 ( 20.0)	3 ( 8.8)	11 ( 14.9)
Nausea	6 ( 15.0)	5 ( 14.7)	11 ( 14.9)
Dyspnoea	7 ( 17.5)	2 ( 5.9)	9 ( 12.2)
Pyrexia	3 ( 7.5)	4 ( 11.8)	7 ( 9.5)
Rash	3 ( 7.5)	4 ( 11.8)	7 ( 9.5)
Dizziness	2 ( 5.0)	4 ( 11.8)	6 ( 8.1)
Influenza	2 ( 5.0)	4 ( 11.8)	6 ( 8.1)
Nasopharyngitis	4 ( 10.0)	2 ( 5.9)	6 ( 8.1)
Vomiting	4 ( 10.0)	2 ( 5.9)	6 ( 8.1)
Abdominal pain	4 ( 10.0)	1 ( 2.9)	5 ( 6.8)
Epistaxis	1 ( 2.5)	4 ( 11.8)	5 ( 6.8)
Fatigue	4 ( 10.0)	1 ( 2.9)	5 ( 6.8)
Hypokalaemia	3 ( 7.5)	2 ( 5.9)	5 ( 6.8)

\*One patient from the Phase 1b clinical trial, who remains on drug, is included.

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.

<sup>a</sup> Coded using MedDRA v 24.0

# Incidence of TEAEs by preferred term: $\geq 5\%$ in total column (Safety Population) - Continued

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	Total (N=74)
Number of subjects with a TEAE	38 ( 95.0)	32 ( 94.1)	70 ( 94.6)
Pneumonia	3 ( 7.5)	2 ( 5.9)	5 ( 6.8)
Pulmonary arterial hypertension	3 ( 7.5)	2 ( 5.9)	5 ( 6.8)
Alanine aminotransferase increased	4 ( 10.0)	0	4 ( 5.4)
Arthralgia	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Aspartate aminotransferase increased	4 ( 10.0)	0	4 ( 5.4)
Back pain	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Complication associated with device	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Flushing	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Iron deficiency	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Nasal congestion	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Pain	1 ( 2.5)	3 ( 8.8)	4 ( 5.4)
Pain in extremity	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Palpitations	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Throat irritation	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Upper respiratory tract infection	2 ( 5.0)	2 ( 5.9)	4 ( 5.4)
Vascular device infection	0	4 ( 11.8)	4 ( 5.4)

\*One patient from the Phase 1b clinical trial, who remains on drug, is included in this group.

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.

<sup>a</sup> Coded using MedDRA v 24.0

# Incidence of Related TEAEs in 2 or More Patients (Safety Population)

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	Total (N=74)
Number of subjects with a related adverse event	16 ( 40.0)	11 ( 32.4)	27 ( 36.5)
Cough	7 ( 17.5)	3 ( 8.8)	10 ( 13.5)
Headache	2 ( 5.0)	3 ( 8.8)	5 ( 6.8)
Throat irritation	3 ( 7.5)	1 ( 2.9)	4 ( 5.4)
Alanine aminotransferase increased	2 ( 5.0)	0	2 ( 2.7)
Aspartate aminotransferase increased	2 ( 5.0)	0	2 ( 2.7)
Fatigue	1 ( 2.5)	1 ( 2.9)	2 ( 2.7)
Thrombocytopenia	0	2 ( 5.9)	2 ( 2.7)

\*One patient from the Phase 1b clinical trial, who remains on drug, is included in this group.

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.

<sup>a</sup> Coded using MedDRA v 24.0

# Incidence of TEAEs Leading to Study Drug Discontinuation (Safety Population)

Preferred term <sup>a</sup>	Placebo Switch (N=40)	Seralutinib Cont. (N=34*)	Total (N=74)
No. with a TEAE leading to d/c of study drug	9 ( 22.5)	3 ( 8.8)	12 ( 16.2)
Cough	4 ( 10.0)	1 ( 2.9)	5 ( 6.8)
Alanine aminotransferase increased	2 ( 5.0)	0	2 ( 2.7)
Throat irritation	1 ( 2.5)	1 ( 2.9)	2 ( 2.7)
Abdominal pain	1 ( 2.5)	0	1 ( 1.4)
Acute respiratory failure	1 ( 2.5)	0	1 ( 1.4)
Aspartate aminotransferase increased	1 ( 2.5)	0	1 ( 1.4)
Blood bilirubin increased	1 ( 2.5)	0	1 ( 1.4)
Confusional state	1 ( 2.5)	0	1 ( 1.4)
Liver function test abnormal	0	1 ( 2.9)	1 ( 1.4)
Nausea	0	1 ( 2.9)	1 ( 1.4)
Vomiting	0	1 ( 2.9)	1 ( 1.4)

\*One patient from the Phase 1b clinical trial, who remains on drug, is included in this group.

Abbreviations: d/c, discontinuation; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.

<sup>a</sup> Coded using MedDRA v 24.0