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Interim TORREY OLE Update and PROSERA Phase 3 Design

July 2023

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I. TORREY 24 Week Data



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)	30 (68.2)	50 (58.1)
Class III	22 (52.4)	14 (31.8)	36 (41.9)
PVR (dyne*s/cm ⁵) – mean (SD)	661.3 (164.91)	675.8 (240.35)	668.7 (205.90)
6MWD (m) – mean (SD)	407.1 (107.02)	408.6 (75.11)	407.9 (91.54)
NT-proBNP (ng/L) – mean (SD)	645.6 (1158.75)	611.0 (714.58)	628.3 (956.83)

Heavily pre-treated patient population

Hit Primary Endpoint Despite FC Imbalance in Drug & Pbo Arms

Mildest baseline PAH disease to see treatment effect*

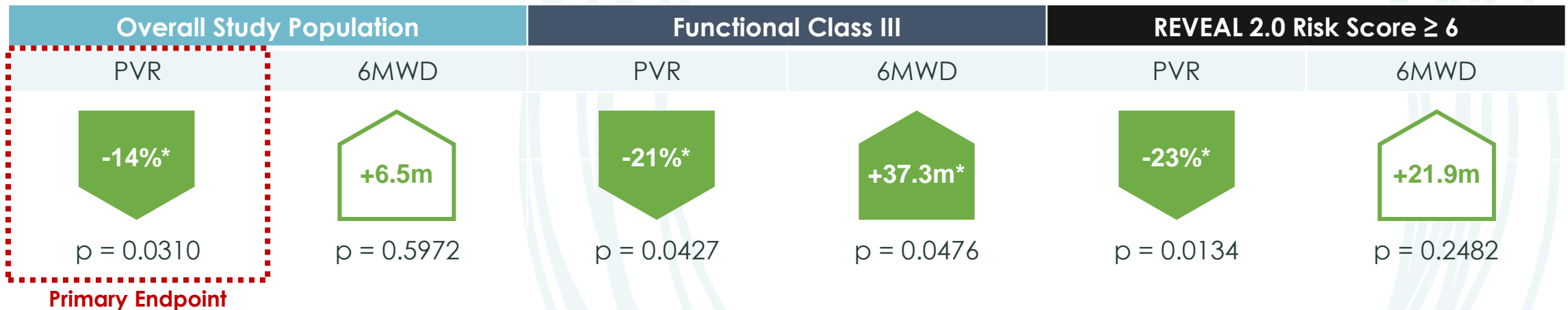
STELLAR Trial Phase 3 NT-proBNP mean baseline was 1,121.1ng/L; PVR was 763.7 dyne*s/cm⁵ (1)

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.

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[§]



- 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⁻⁵ (p = 0.2601) from baseline.

II. New Developments



New Developments in the Seralutinib Program

- **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 Δ 6MWD & Δ NT-proBNP
 - Increased magnitude of effect in Phase 3 target population
 - Attractive safety profile for chronic treatment
- **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**
 - Anticoagulants allowed with important patient safety guardrails

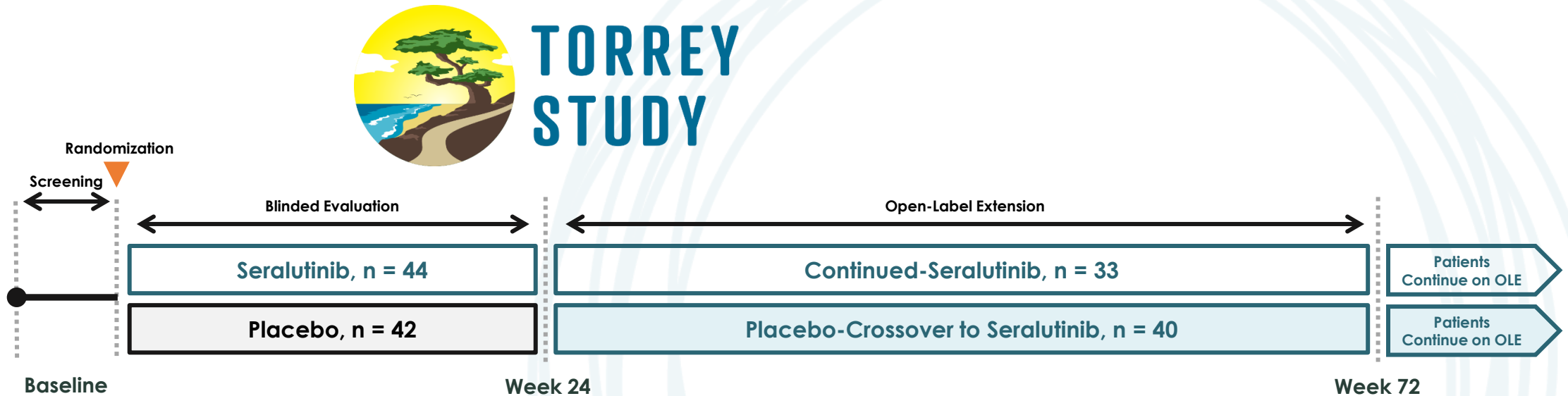
III. Interim TORREY OLE Extension Results

*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/cm⁵

- 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/cm⁵

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

OLE PVR Data Point

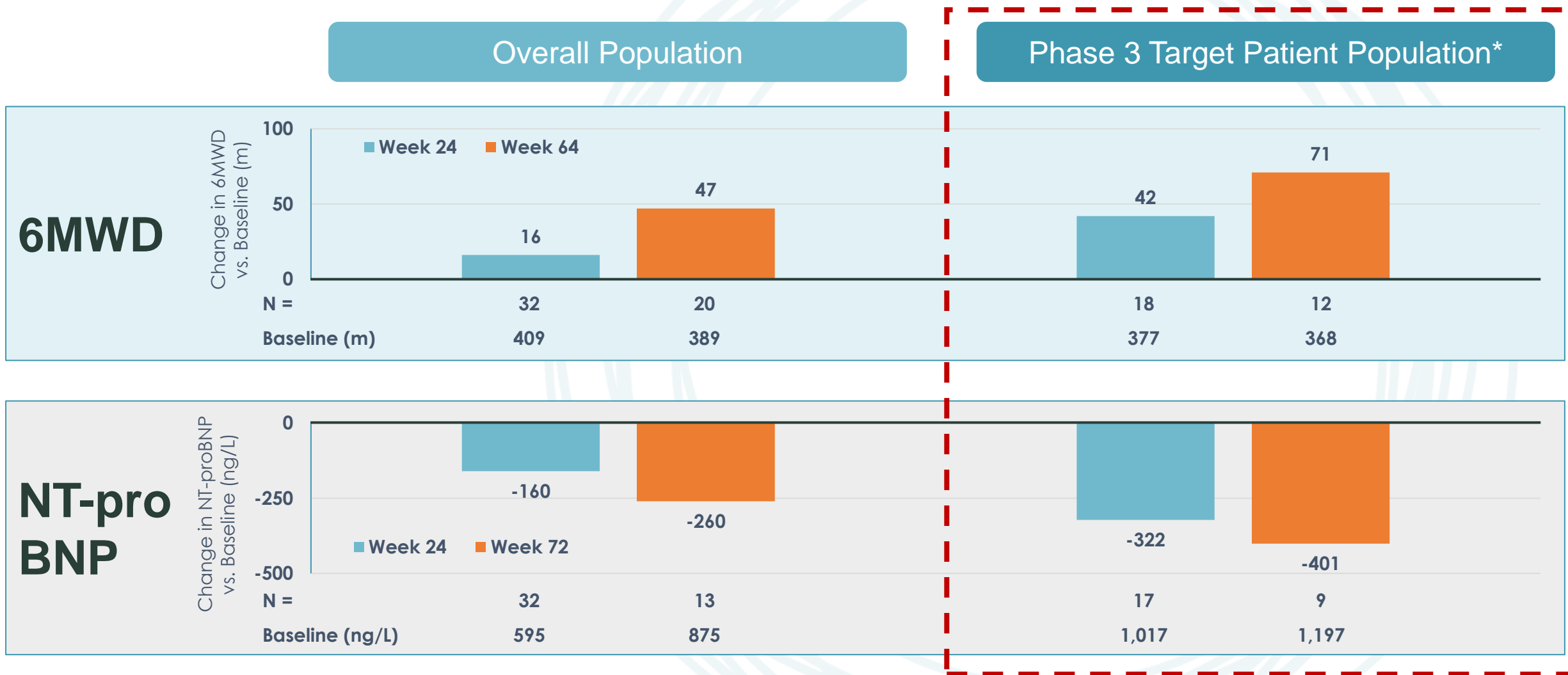
Week 72

Median Change in PVR
vs. Baseline:

 **-142.5**
dyne*s/cm⁵

- 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/cm⁵

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

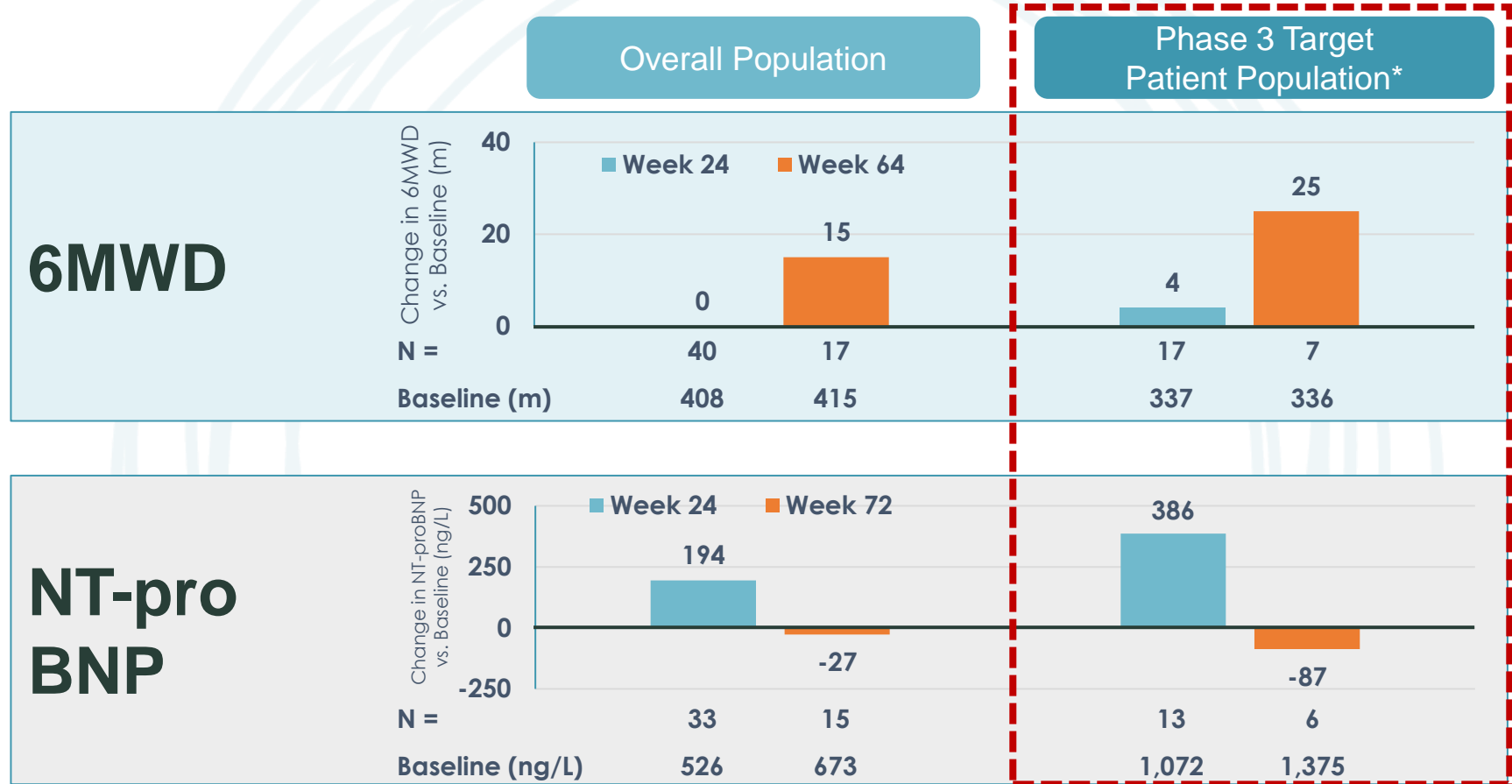


* REVEAL Lite 2 Risk Score ≥ 5 at TORREY baseline.
6MWD = six-minute walk distance; NT-proBNP = N-terminal pro B-type natriuretic peptide.

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 ≥ 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

IV. 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 Study Overview

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

PROSERA Phase 3 Study Population



PROSERA STUDY

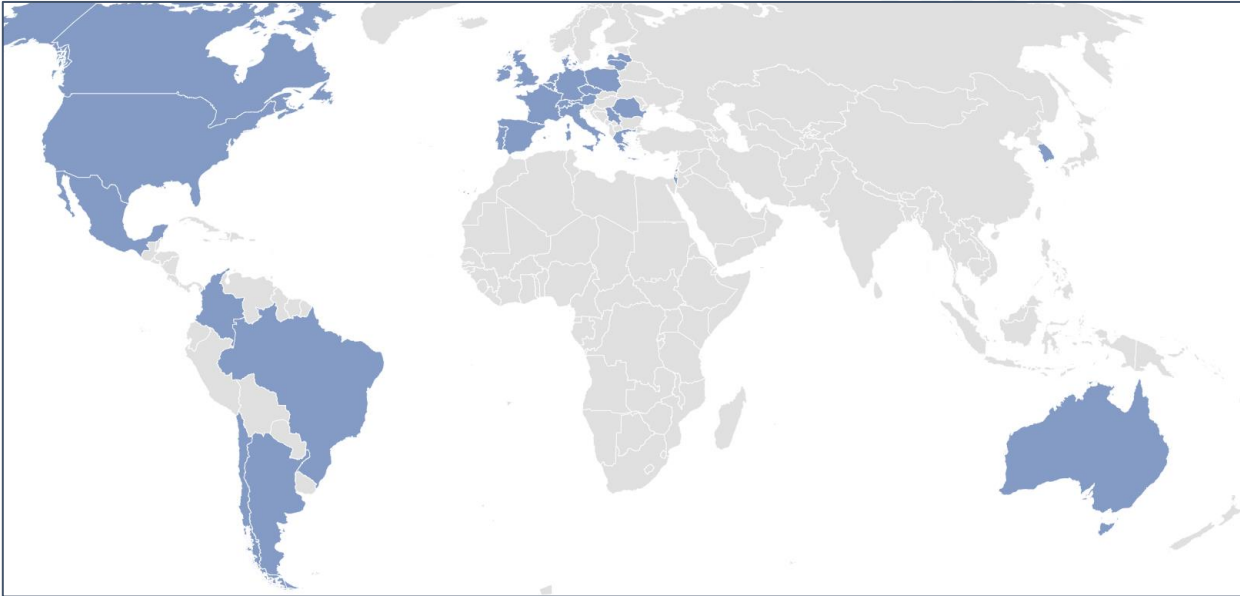
Key Inclusion Criteria

- Adults ≥ 18 and ≤ 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 ≥ 5
or $NT\text{-}proBNP \geq 300 \text{ ng}/\text{L}^*$
- 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

Broad Global Footprint with Trusted Sites and Clinical Partners



US and Canada: 50+ Sites

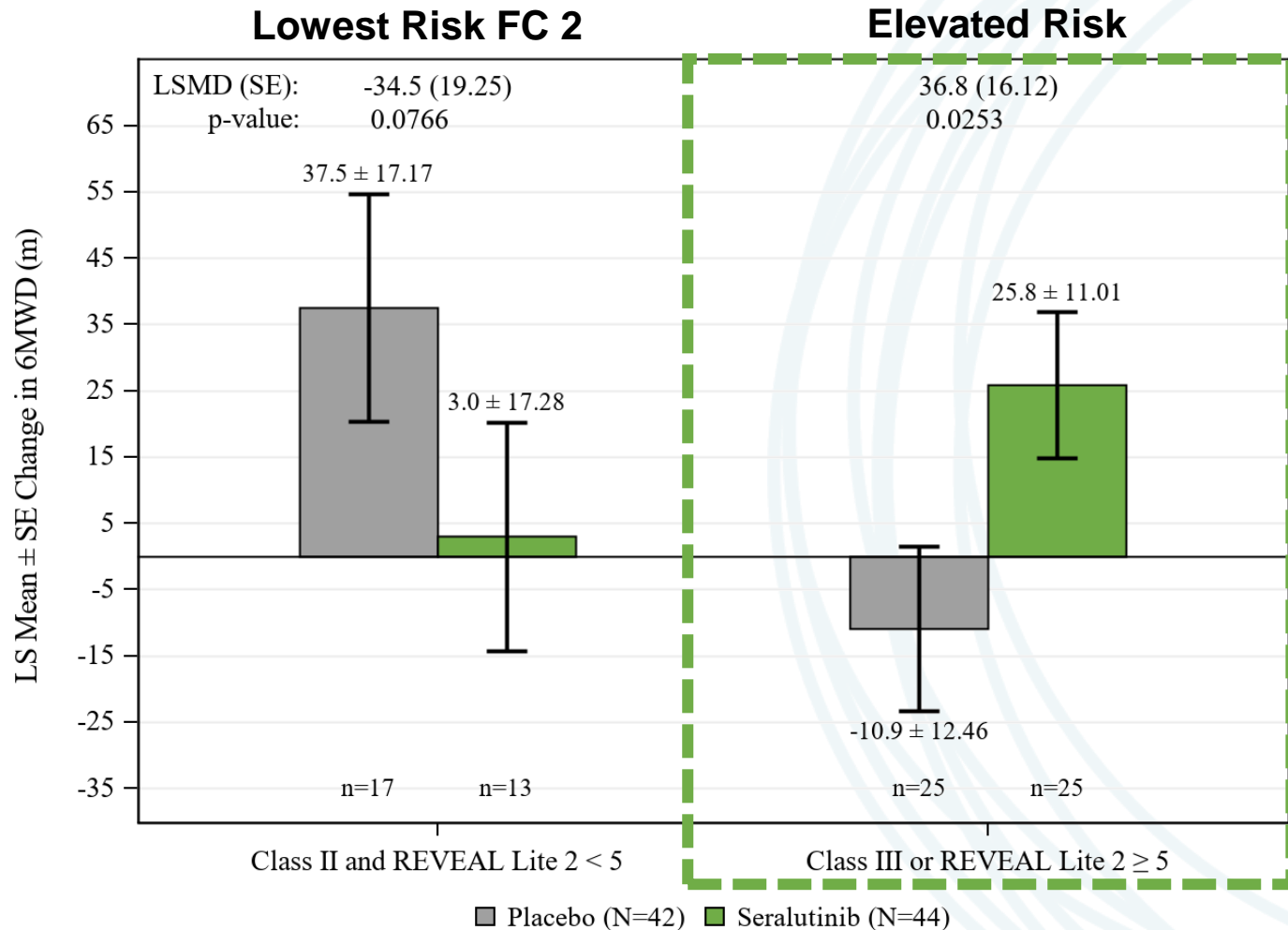
Latin America: ~25 Sites

Europe: 75+ Sites

Asia Pacific: 10+ Sites

- 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

Further Validation of REVEAL Lite 2 Enrichment for Phase 3 *TORREY* Week 24 Δ 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

Appendix I – OLE Safety



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

Preferred term ^a	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.

^a Coded using MedDRA v 24.0

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

Preferred term ^a	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.

^a Coded using MedDRA v 24.0

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

Preferred term ^a	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.

^a Coded using MedDRA v 24.0

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

Preferred term ^a	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.

^a Coded using MedDRA v 24.0