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): December 6, 2022

GOSSAMER BIO, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-38796	47-5461709
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3013 Science Park Road
San Diego, California, 92121

(Address of Principal Executive Offices) (Zip Code)

(858) 684-1300
(Registrant's Telephone Number, Including Area Code)

N/A
(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 Instructions 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 Stock, $0.0001 par value per share	GOSS	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 8.01 Other Events.

On December 6, 2022, Gossamer Bio, Inc. (the "Company") announced topline results from its Phase 2 TORREY study of seralutinib in patients with pulmonary arterial hypertension (PAH). Seralutinib is a tyrosine kinase inhibitor targeting PDGFRα/β, CSF1R, and c-KIT, specifically designed to be delivered via dry powder inhaler for the treatment of pulmonary hypertension.

The Phase 2 TORREY study enrolled 86 patients with WHO Functional Class (FC) II or III PAH, with 42 randomized to the placebo arm and 44 randomized to the seralutinib arm. The primary endpoint of the study was change from baseline to Week 24 in pulmonary vascular resistance (PVR). The secondary endpoint was change in six-minute walk distance (6MWD) from baseline to Week 24. Patients remained on their background PAH therapies during the study. At baseline, 57% of patients were on background triple therapy, consisting of three classes of vasodilator treatments. The mean baseline PVR and 6MWD of randomized patients were ~669 dynes*s/cm^5 and ~408 meters, respectively. The treatment and placebo arms were generally well balanced, except for baseline WHO Functional Class: 20 FC II and 22 FC III patients were randomized to the placebo arm, while 30 FC II and 14 FC III patients were randomized to the seralutinib arm.

The Phase 2 TORREY study met its primary endpoint with a mean difference in PVR between the placebo and seralutinib arms of -96.1 dynes ($p = 0.0310$), equating to a placebo-corrected improvement of 14.3%. In the secondary endpoint, an observed mean difference in 6MWD between placebo and seralutinib of 6.5 meters numerically favored the seralutinib arm. Changes in PVR favored seralutinib across all pre-specified patient sub-group analyses, demonstrating consistency in the hemodynamic outcomes observed in the study. Likewise, changes in 6MWD favored seralutinib in the majority of pre-specified sub-groups. Enhanced effects for both PVR and 6MWD were observed in patients with more severe baseline disease, as defined by WHO Functional Class and REVEAL 2.0 Risk Scores. In FC III patients, a 21% reduction in PVR ($p = 0.0427$) and 37m improvement in 6MWD ($p = 0.0476$) were observed for the seralutinib arm versus placebo. In patients with a baseline REVEAL 2.0 Risk Score of 6 or greater, a 23% reduction in PVR ($p = 0.0134$) and 22m improvement in 6MWD ($p = 0.2482$) were observed for the seralutinib arm versus placebo.

Seralutinib treatment resulted in a statistically significant reduction in NT-proBNP, a biomarker of right heart stress, as early as 12 weeks, increasing to a 408.3 ng/L mean difference from placebo at Week 24 ($p = 0.0012$). This biomarker change was accompanied by clinically relevant and statistically significant changes for seralutinib versus placebo in key assessments of right heart structure and function, including right atrium area, right ventricle free wall strain, and pulmonary artery compliance.

Seralutinib was generally well tolerated in the TORREY study, with treatment emergent adverse events (TEAEs) reported in 36 (86%) and 41 (93%) of the patients in the placebo and seralutinib arms, respectively. The vast majority of TEAEs reported in the study were mild to moderate in nature. In the seralutinib arm, there was one serious adverse event (SAE) related to study drug reported, while no SAEs related to study drug were reported in the placebo arm. The most frequently reported TEAE in the study was cough, reported in 16 (38%) and 19 (43%) of the patients in the placebo and seralutinib arms, respectively. Of the 19 patients reporting cough in the seralutinib arm, 17 experienced mild cough, while 2 experienced moderate cough. Of note, the most frequently reported TEAEs in the IMPRES Phase 3 study of imatinib in PAH, including nausea, peripheral edema, diarrhea, and vomiting, were observed at substantially lower frequency in the TORREY study, and reported cases were generally well balanced between the seralutinib and placebo arms. No cases of subdural hematoma were reported in the study.

The slides attached as Exhibit 99.1 to this Current Report contain certain additional information related to the clinical data results discussed above and are incorporated herein by this reference. The Company intends to present the slides during a conference call and live webcast with the investment community on December 6, 2022, at 8:00 a.m. ET.

Forward-Looking Statements

Gossamer cautions you that statements contained in this current report regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include: the potential of seralutinib to serve PAH patients and the potential for seralutinib to be differentiated from other PAH therapies. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of its plans will be achieved. Actual results may differ from those set forth in this current report due to the risks and uncertainties inherent in Gossamer's business, including, without limitation: topline results Gossamer reports is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; potential delays in the commencement, enrollment and completion of clinical trials; comparative safety information is not based on a head-to-head comparison and differences exist between study designs and subject characteristics which could confound the results; disruption to Gossamer's operations from the ongoing COVID-19 pandemic, including clinical trial delays and clinical site staff shortages; Gossamer's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of Gossamer's clinical trials and preclinical studies for its product candidates; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Gossamer's ability to obtain and maintain intellectual property protection for its product candidates; Gossamer's ability to comply with its obligations in collaboration agreements with third parties or the agreements under which it licenses intellectual property rights from third parties; Gossamer may use its capital resources sooner than it expects; and other risks described under the heading "Risk Factors" in documents the Company files from time to time with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Gossamer undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide Presentation entitled "Phase 2 TORREY Study Topline Results"

SIGNATURES

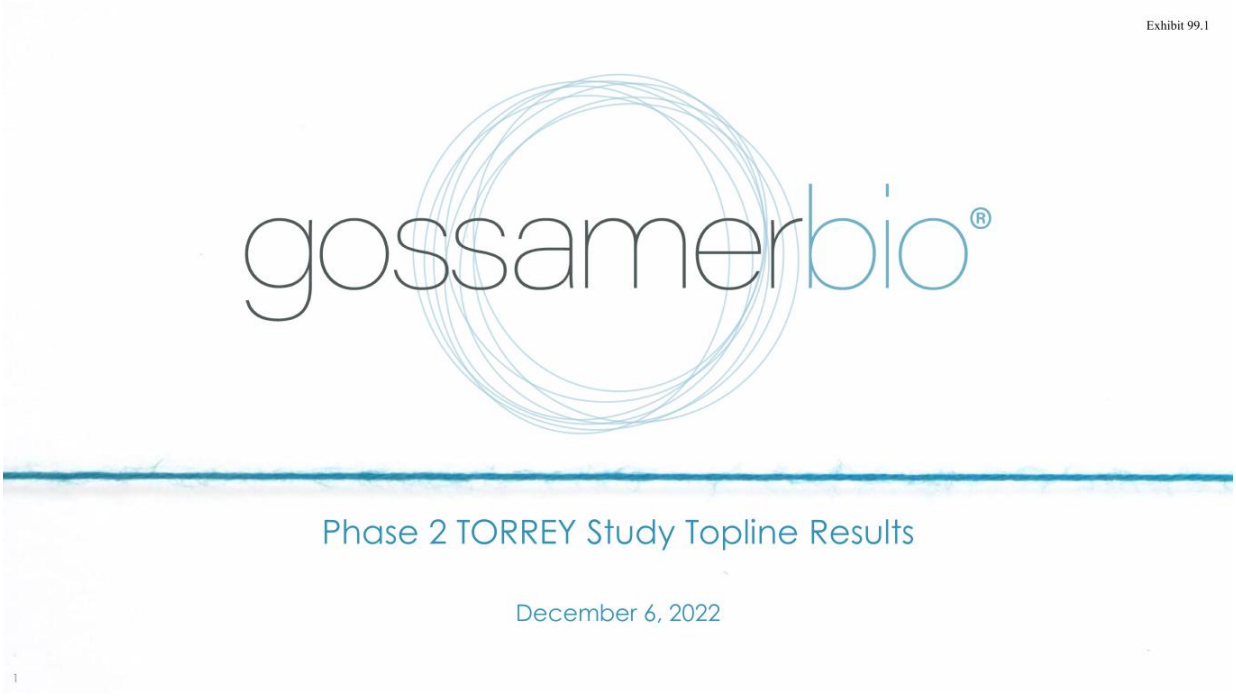
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GOSSAMER BIO, INC.

Date: December, 6 2022

By: /s/ Christian Waage
Christian Waage
Executive Vice President, Technical Operations & Administration

Exhibit 99.1



Phase 2 TORREY Study Topline Results

December 6, 2022

Forward Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding the potential of seralutinib to serve patients with pulmonary arterial hypertension (PAH), the potential for seralutinib to be differentiated from other PAH therapies, plans to complete regulatory interactions regarding the Phase 2 TORREY study and the timing thereof, plans to commence a global registrational Phase 3 Program in PAH and the timing thereof, and plans to commence a development program in World Health Organization Group 3 pulmonary hypertension (PH) and the timing thereof, 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. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These known risks and uncertainties are described in detail in our filings with the Securities and Exchange Commission (the "SEC") from time to time. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and we undertake no obligation to revise or update this presentation to reflect events or circumstances after the date hereof.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. These data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. Additionally, comparative safety information presented herein is not based on a head-to-head comparison and differences exist between study designs and subject characteristics which could confound the results.

Presenters for Today's Call

Gossamer Bio	
Faheem Hasnain	Co-Founder, Chairman, & Chief Executive Officer
Richard Aranda, MD	Chief Medical Officer
Robert Roscigno, PhD	VP, Clinical Development
Larry Zisman, MD	Sr Dir, Clinical Development
Ed Parsley, DO	Consultant Pulmonologist
Matt Cravets	SVP, Biometrics
Laura Carter, PhD	Chief Scientific Officer
Caryn Peterson	EVP, Regulatory Affairs
Bryan Giraudo	COO & CFO

Guest Speakers

Ardeschir Ghofrani, MD*
Professor of Pulmonary Vascular Research, Justus Liebig University; Head of the Pulmonary Hypertension Division, University Hospital Giessen

Raymond Benza, MD*
Professor of Medicine, Division of Cardiovascular Medicine, The Ohio State University

*Drs. Ghofrani and Benza are investigators in the TORREY Study and are paid consultants to Gossamer.

TORREY Study Topline Results Highlights

- **Met primary endpoint of statistically significant reduction in PVR in a heavily treated, prevalent study population**
- Functional outcome, six-minute walk test, **favored seralutinib**, though study was neither powered nor designed for this endpoint
- **Statistically significant reduction in NT-proBNP**, coupled with **significant changes observed in right heart parameters**†
- **Well tolerated**, avoiding side effect profile associated with systemic imatinib in PAH

† As assessed by ECHO.

TORREY Study Topline Results Highlights, Cont.

- **Consistent benefit** across pre-specified sub-groups **in favor of seralutinib** with **enhanced effects in patients with more severe disease at baseline**§

Overall Study Population		Functional Class III		REVEAL 2.0 Risk Score ≥ 6	
PVR	6MWD	PVR	6MWD	PVR	6MWD
-14%*	+6.5m	-21%*	+37.3m*	-23%*	+21.9m
p = 0.0310	p = 0.5972	p = 0.0427	p = 0.0476	p = 0.0134	p = 0.2482

- Consistently favorable results for hemodynamic and ECHO endpoints

* = 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).

Disease Overview and Available Treatments

PAH is a Rare and Progressive Disease

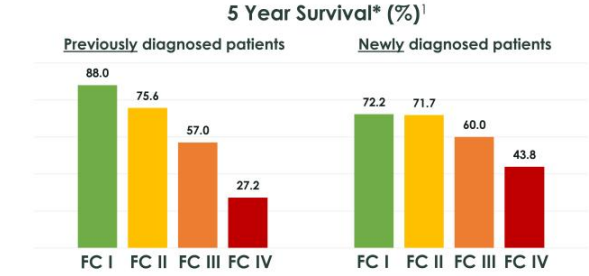
- PAH is a rare, progressive disease[1,2] with an estimated worldwide prevalence of 5-25 cases per million per year[3]
- PAH has no known cure, is associated with poor survival, and has a debilitating impact on the health-related quality of life of patients and caregivers[1,2,4,5]
- PAH is characterized by vascular remodeling[6,7]
  - cellular overgrowth, narrowing and thickening of pulmonary arterioles, and formation of pathologic lesions
  - underlying pathologic mechanisms include inflammation, proliferation, and fibrosis
  - leads to obstructed pulmonary blood flow, increased PVR, ultimately right heart failure and death
- Current treatment approaches are primarily vasodilatory[8-10]
- A significant unmet need exists for new therapies that address the underlying pathological mechanisms of PAH

1 Mathai SC et al. Ann Am Thorac Soc. 2016;13:31-9; **2** Farber HW et al. Chest. 2015;148:1043-54; **3** Maron BA & Galie N et al. JAMA Cardiol 2016; 1:1056-1065; **4** Fernandes CJ et al.Health Qual Life Outcomes. 2014;12:130; **5** Delcroix M & Howard L. Eur Respir Rev 2015; 24:621-629; **6** Humbert M et al. Eur Respir J 2019; 53: 1801887; **7** Schmermuly RT et al. Nat Rev Cardiol 2011; 8:443-455; **8** Humbert, et al. Circulation. 2014, 130:2189-2208; **9** Maron BA et al. Am J Resp Crit Care Med 2021; 203(12):1472-1487; **10** Vasquez ZGS & Ringer JR. Lung 2020; 198:581-596

Functional Class Correlates With Risk Status & Predicts Survival

- Analysis of REVEAL Registry shows that 5-year survival remains poor despite progress in PAH-specific therapy options and improved patient support strategies
- Functional Class is predictive of survival

WHO Functional Assessment for Pulmonary Hypertension			
Class I	**Class II**	**Class III**	**Class IV**
No limitation of physical activity	Slight limitation of physical activity	Marked limitation of physical activity	Inability to carry out physical activity



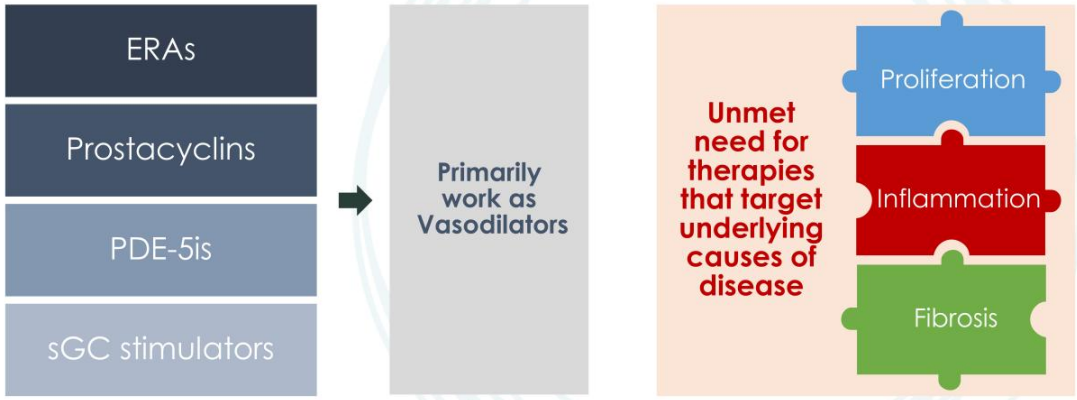
1 Farber HW et al. CHEST 2015; 148:1043. Functional Class: Modified New York Heart Association/WHO Functional Classification for PH. Previously diagnosed subjects are those whose diagnostic RHC fell >90 d before enrollment. Newly diagnosed subjects are those whose diagnostic RHC fell within 90 d before enrollment. REVEAL, Registry to Evaluate Early and Long-term PAH Disease Management. *Kaplan-Meier survival estimates from time of enrollment.

The Clinical Goal of PAH Therapy is to Achieve Low Risk Status[1]

- Low risk status usually associated with[1]
  - Good exercise capacity
  - Good quality of life
  - Good right ventricular function
  - Low mortality risk
- Patients categorized as low risk[1]
  - Have est. 1-year mortality <5%
  - Present with non-progressive disease in WHO-FC I/II with 6MWD >440m and no signs of clinically relevant RV dysfunction

6MWD, 6-minute walk distance; FC, functional class; RV, right ventricle. 1 Galiè N et al. Eur Respir J. 2015;46:903-975.

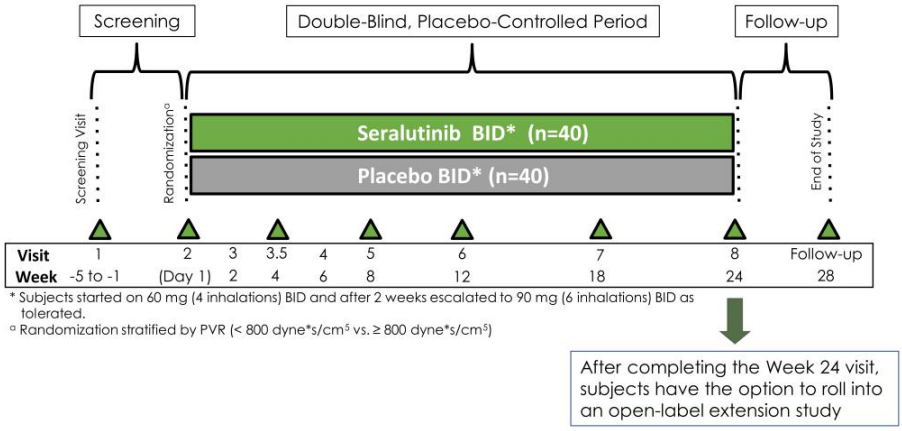
What Do Currently Available Therapies Do?



ERA: endothelin receptor agonist; ET: endothelin; PDE-5i: phosphodiesterase-5 inhibitor; PGI2: sGC stim: soluble guanylate cyclase stimulators.
Source: Adapted from Humbert, et al., N Engl J Med 2004, 351:1425; LeVarge, et al. Ther Clin Risk Manag. 2015; Jing, et al. AJRCCM, 2011; Channick, et al. Lancet, 2001.

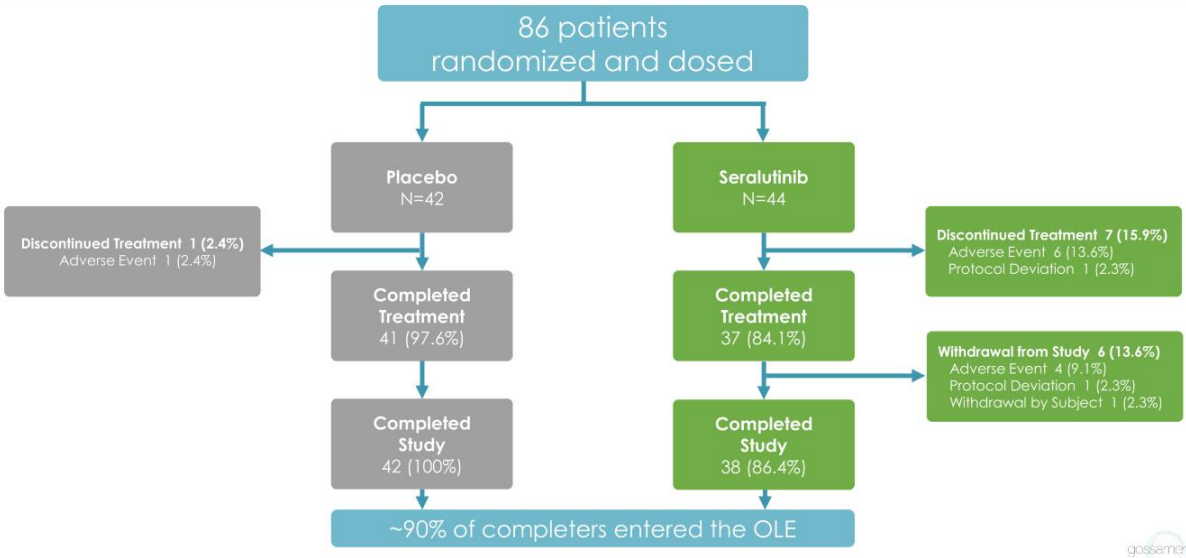
Study Design and Baseline Characteristics

Study Design



▲ Indicates in-clinic visit.
Abbreviations: BID, twice-daily; PVR, pulmonary vascular resistance.

Patient Disposition



Baseline Demographics (ITT Population)

Characteristic	Placebo (N=42)	Seralutinib (N=44)	Total (N=86)
Age (years) – mean (SD)	49.5 (11.81)	48.3 (12.70)	48.8 (12.22)
Sex – n (%)			
Female	38 (90.5)	40 (90.9)	78 (90.7)
Male	4 (9.5)	4 (9.1)	8 (9.3)
Race – n (%)			
White	37 (88.1)	37 (84.1)	74 (86.0)
Black or African American	1 (2.4)	0	1 (1.2)
Asian	2 (4.8)	4 (9.1)	6 (7.0)
Other	2 (4.8)	3 (6.8)	5 (5.8)
Ethnicity – n (%)			
Hispanic or Latino	6 (14.3)	8 (18.2)	14 (16.3)
Not Hispanic or Latino	34 (81.0)	36 (81.8)	70 (81.4)
Not reported	2 (4.8)	0	2 (2.3)
Region – n (%)			
North America	30 (71.4)	29 (65.9)	59 (68.6)
Western Europe	10 (23.8)	11 (25.0)	21 (24.4)
Asia Pacific	1 (2.4)	4 (9.1)	5 (5.8)
Eastern Europe	1 (2.4)	0	1 (1.2)

Abbreviations: ITT, Intention-to-treat; SD, standard deviation.

Baseline Background PAH Medication Use (ITT Population)

Characteristic	Placebo (N=42)	Seralutinib (N=44)	Total (N=86)
Number of 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)
Prostacyclin/Prostacycin Receptor Agonist use – n (%)			
None	13 (31.0)	15 (34.1)	28 (32.6)
Monotherapy	1 (2.4)	1 (2.3)	2 (2.3)
Double therapy	4 (9.5)	3 (6.8)	7 (8.1)
Triple therapy	24 (57.1)	25 (56.8)	49 (57.0)
Parenteral Prostacyclin	19 (45.2)	19 (43.1)	38 (44.2)
Oral	10 (23.8)	10 (22.7)	20 (23.3)

Abbreviations: ITT, Intention-to-treat.

Baseline Disease Characteristics (ITT Population)

Characteristic	Placebo (N=42)	Seralutinib (N=44)	Total (N=86)
Age at PAH diagnosis (years) – mean (SD)	41.2 (11.65)	40.7 (15.84)	40.9 (13.87)
Years since PAH diagnosis – mean (SD)	8.78 (7.218)	8.07 (7.074)	8.41 (7.111)
PAH classification – n (%)			
Idiopathic	22 (52.4)	20 (45.5)	42 (48.8)
Heritable	5 (11.9)	10 (22.7)	15 (17.4)
Associated with:			
CTD	11 (26.2)	6 (13.6)	17 (19.8)
Anorexigen use	0	1 (2.3)	1 (1.2)
Methamphetamine use	4 (9.5)	4 (9.1)	8 (9.3)
Corrected congenital shunts	0	3 (6.8)	3 (3.5)
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)
REVEAL 2.0 Risk Score ≥ 6 – n (%)	17 (40.5)	20 (45.5)	37 (43.0)
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)

Abbreviations: 6MWD, six-minute walk distance; CTD, connective tissue disease; FC, functional class; NT-proBNP, N-terminal pro B-type natriuretic peptide; PAH, pulmonary arterial hypertension; PVR, pulmonary vascular resistance; WHO, World Health Organization; ITT, Intention-to-treat.

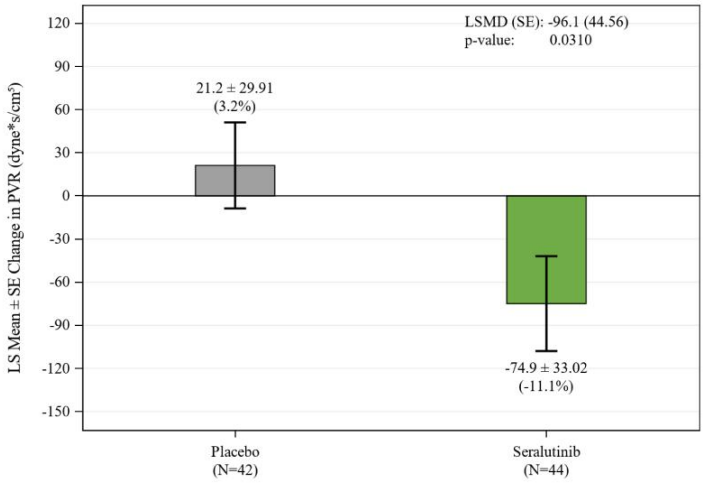
Baseline Demographics and Disease Characteristics *by Baseline WHO FC* (ITT Population)

	Baseline WHO FC Class II			Baseline WHO FC Class III		
Characteristic	Placebo (N=20)	Seralutinib (N=30)	Total (N=50)	Placebo (N=22)	Seralutinib (N=14)	Total (N=36)
Age (years) – mean (SD)	47.6 (11.69)	47.7 (13.42)	47.7 (12.63)	51.1 (11.94)	49.4 (11.40)	50.4 (11.60)
Female – n (%)	19 (95.0)	27 (90.0)	46 (92.0)	19 (86.4)	13 (92.9)	32 (88.9)
Race, White – n (%)	19 (95.0)	24 (80.0)	43 (86.0)	18 (81.8)	13 (92.9)	31 (86.1)
Region, North America – n (%)	13 (65.0)	20 (66.7)	33 (66.0)	17 (77.3)	9 (64.3)	26 (72.2)
Years since PAH diagnosis – mean (SD)	9.60 (7.262)	8.40 (6.961)	8.88 (7.034)	8.02 (7.263)	7.36 (7.527)	7.76 (7.266)
PAH classification – n (%)						
Idiopathic	11 (55.0)	16 (53.3)	27 (54.0)	11 (50.0)	4 (28.6)	15 (41.7)
Heritable	4 (20.0)	6 (20.0)	10 (20.0)	1 (4.5)	4 (28.6)	5 (13.9)
Associated with CTD	5 (25.0)	5 (16.7)	10 (20.0)	6 (27.3)	1 (7.1)	7 (19.4)
REVEAL 2.0 Risk Score ≥ 6 – n (%)	**4 (20.0)**	**11 (36.7)**	**15 (30.0)**	**13 (59.1)**	**9 (64.3)**	**22 (61.1)**
PVR (dyne*s/cm^5) – mean (SD)	638.3 (161.85)	689.9 (265.72)	669.3 (229.34)	682.2 (168.62)	645.7 (179.29)	668.0 (171.25)
6MWD (m) – mean (SD)	**455.5 (63.96)**	**425.5 (62.98)**	**437.5 (64.45)**	**363.2 (120.05)**	**372.4 (87.97)**	**366.8 (107.43)**
NT-proBNP (ng/L) – mean (SD)	**406.8 (798.39)**	**609.9 (715.31)**	**525.3 (749.58)**	**873.0 (1403.06)**	**613.3 (742.17)**	**773.7 (1187.34)**
On 3 background therapies – n (%)	11 (55.0)	18 (60.0)	29 (58.0)	13 (59.1)	7 (50.0)	20 (55.6)
ERA + PDE-5i + Prostacyclins/PRA	8 (40.0)	16 (53.3)	24 (48.0)	10 (45.5)	6 (42.9)	16 (44.4)
ERA + sGC + Prostacyclins/PRA	3 (15.0)	2 (6.7)	5 (10.0)	3 (13.6)	1 (7.1)	4 (11.1)

Abbreviations: ITT, Intention-to-treat; SD, standard deviation; CTD, connective tissue disease; PVR, pulmonary vascular resistance; 6MWD, 6-minute walk distance; NT-proBNP; N-terminal pro B-type natriuretic peptide; WHO, World Health Organization; FC, functional class.

Primary Endpoint: Change From Baseline in PVR

Primary Endpoint: Seralutinib Significantly Reduced PVR at Week 24 (ITT Population)



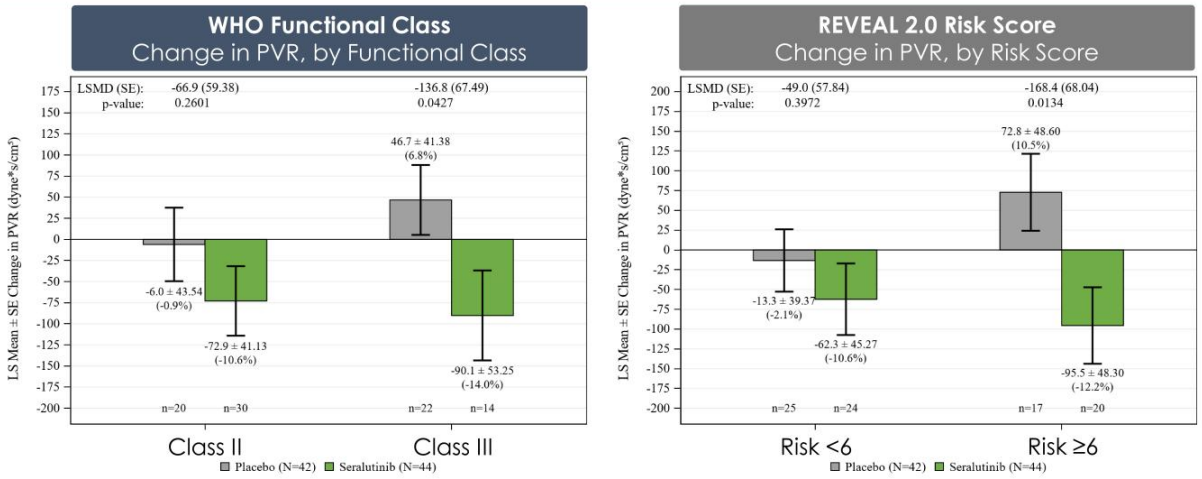
Abbreviations: ANCOVA, analysis of covariance; LS, least squares; LSMD, least squares mean difference; ITT, intent-to-treat; PVR, pulmonary vascular resistance.
Note: Based on an ANCOVA model with multiple imputation.
Source: Data on file.

Seralutinib Consistently Reduced PVR Across All Pre-Specified Sub-Groups (ITT Population)

Subgroup	Placebo N	Seralutinib N	LSMD (95% CI)[a]	p-value[a]
Overall	42	44	-96.1 (-183.5, -8.8)	0.0310
Sex				
Female	38	40	-97.5 (-190.2, -4.9)	0.0390
PAH background medications				
< 3	18	19	-105.8 (-235.4, 23.9)	0.1099
≥ 3	24	25	-89.1 (-205.8, 27.5)	0.1343
Prostacyclins at baseline				
Yes	29	29	-93.9 (-201.9, 14.1)	0.0885
No	13	15	-105.4 (-252.8, 41.9)	0.1609
Age groups				
< median (47 years)	19	24	-143.6 (-268.1, -19.0)	0.0239
≥ median (47 years)	23	20	-49.1 (-171.1, 72.9)	0.4303
< 65 years	37	36	-84.0 (-178.1, 10.1)	0.0801
≥ 65 years	5	8	-192.2 (-423.9, 39.5)	0.1040
Race				
white	37	37	-100.3 (-192.1, -8.4)	0.0324
non-white	5	7	-44.8 (-290.7, 201.1)	0.7210
Region				
North America	30	29	-65.9 (-172.6, 40.8)	0.2262
Rest of world	12	15	-164.7 (-316.8, -12.7)	0.0337
PVR strata				
< 800 dyne*s/cm^5	34	34	-91.0 (-186.1, 4.1)	0.0606
≥ 800 dyne*s/cm^5	8	10	-119.6 (-332.9, 93.6)	0.2712
WHO Functional Class				
II	20	30	-66.9 (-183.3, 49.5)	0.2601
III	22	14	-136.8 (-269.1, -4.5)	0.0427
Connective Tissue Disease				
yes	11	6	-55.8 (-294.4, 182.7)	0.6459
no	31	38	-95.5 (-190.3, -0.8)	0.0482
REVEAL 2.0 risk score				
< 6	25	24	-49.0 (-162.3, 64.4)	0.3972
≥ 6	17	20	-168.4 (-301.7, -35.0)	0.0134

Abbreviations: ANCOVA, analysis of covariance; FC, functional class; PVR, pulmonary vascular resistance; WHO, World Health Organization; LSMD, least squares mean difference.
[a] Based on an ANCOVA model with multiple imputation.
Source: Data on file.

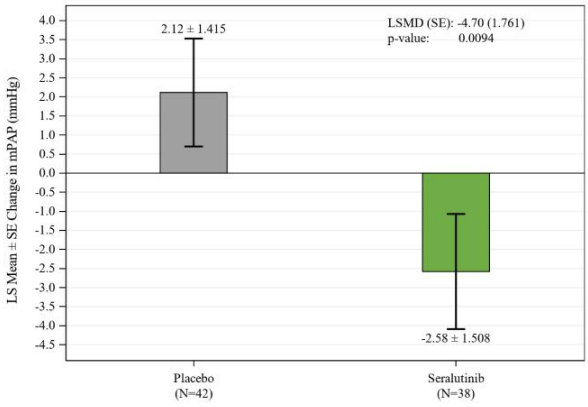
Seralutinib's Effect on PVR was More Pronounced in Patients with More Severe Disease at Baseline (ITT Population)



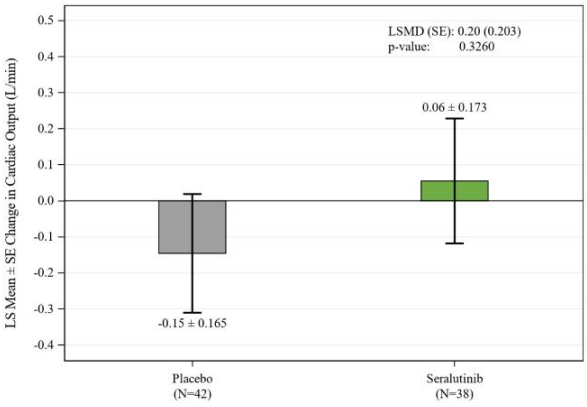
Abbreviations: ANCOVA, analysis of covariance; LS, least squares; LSMD, least squares mean difference; PVR, pulmonary vascular resistance; WHO, World Health Organization.
Note: Based on ANCOVA modelling.
Source: Data on file.

Observed Reduction in PVR Mainly Driven by Reduction in mPAP

Change in mPAP from Baseline to Week 24



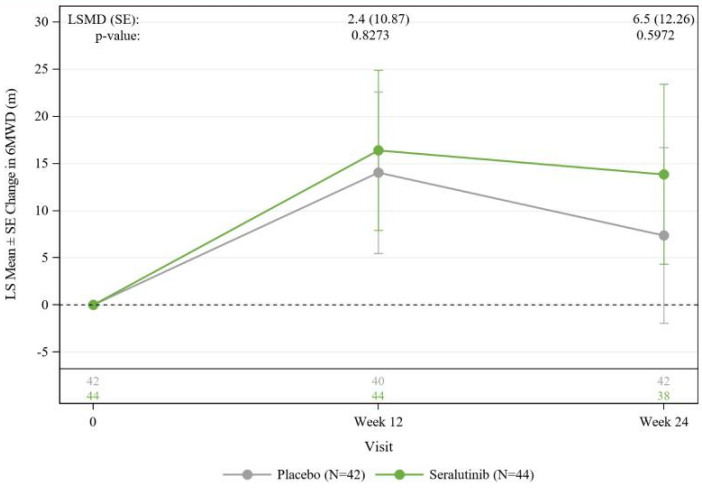
Change in CO from Baseline to Week 24



Abbreviations: ANCOVA, analysis of covariance; CO, cardiac output; LS, least squares; LSMD, least squares mean difference; mPAP, mean pulmonary arterial pressure; RHC, right heart catheterization; PVR, pulmonary vascular resistance.
Note: Based on ANCOVA modelling using observed cases.
Source: Data on file.

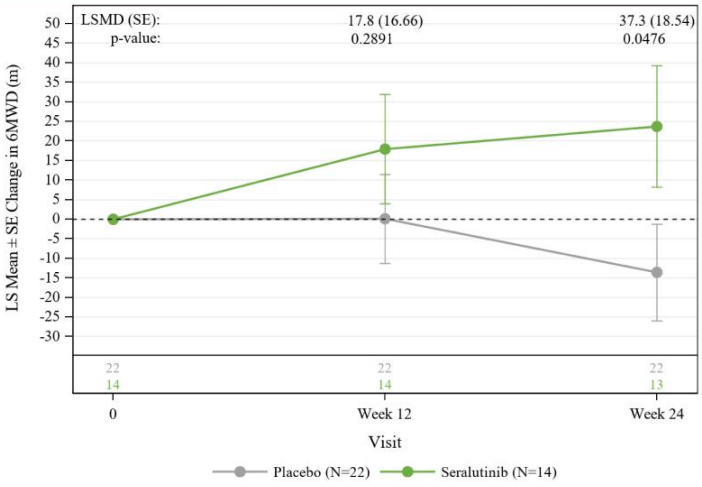
Secondary Endpoint: Change From Baseline in 6MWD

Secondary Endpoint: Change in 6MWD from Baseline to Each Visit (ITT Population)



Abbreviations: 6MWD, six-minute walk distance; FC, functional class; MMRM, mixed-effects model with repeated measures; WHO, World Health Organization.
Note: Based on a MMRM model.
Source: Data on file.

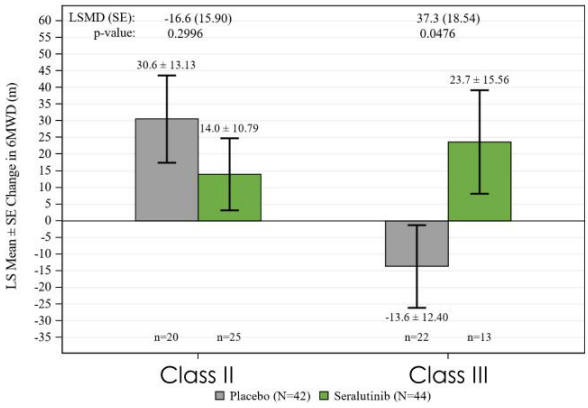
Secondary Endpoint: Change in 6MWD from Baseline to Each Visit for Baseline FC III Patients (ITT Population)



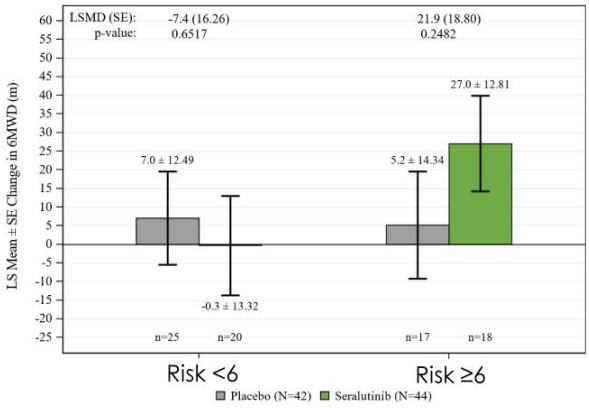
Abbreviations: 6MWD, six-minute walk distance; FC, functional class; MMRM, mixed-effects model with repeated measures; WHO, World Health Organization.
Note: Based on a MMRM model.
Source: Data on file.

Change in 6MWD by Functional Class and REVEAL 2.0 Risk Score (ITT Population)

Functional Class
Change in 6MWD, by Functional Class



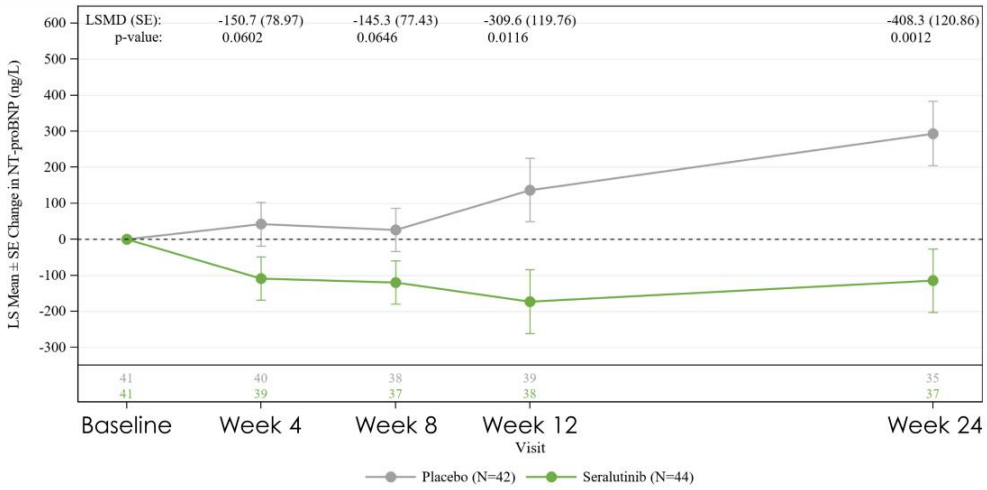
REVEAL 2.0 Risk Score
Change in 6MWD, by Risk Score



Abbreviations: 6MWD, six-minute walk distance; FC, functional class; LS, least squares; LSMD, least squares mean difference; MMRM, mixed-effects model with repeated measures; WHO, World Health Organization.
Note: Based on MMRM modelling.
Source: Data on file.

Exploratory Endpoints & REVEAL 2.0 Risk Score Change

Seralutinib Treatment Led to Statistically Significant Reduction in NT-proBNP (ITT Population)



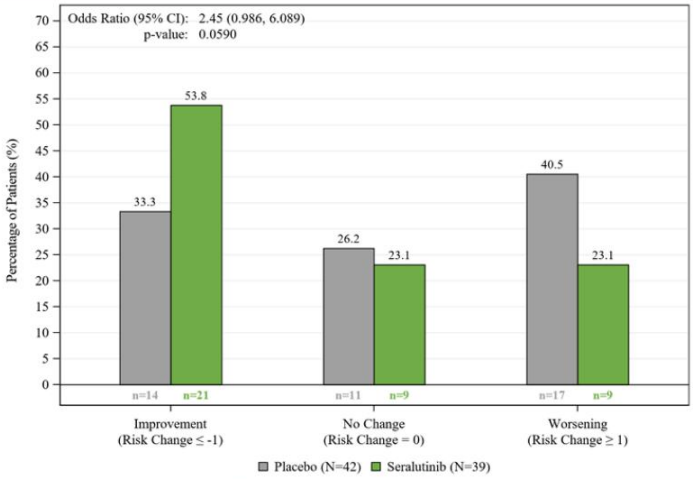
Abbreviations: FC, functional class; LS, least squares; LSMD, least squares mean difference; MMRM, mixed-effects model with repeated measures; NT-proBNP, N-terminal pro B-type natriuretic peptide.
Note: Based on a MMRM model.
Source: Data on file.

Centrally-Read RHC and ECHO Results at Week 24 Consistently Favored Seralutinib (ANCOVA – Observed Cases)

Endpoint	LS Mean Difference (95% CI)	Statistically Significant Result Favoring Seralutinib (p ≤ 0.05)	Point Estimate Favoring Seralutinib	p-value
Right Atrium Area (cm^2)	**-1.99 (-3.783, -0.206)**	✓	✓	**0.0293***
RV Free Wall Strain (%)	**-2.64 (-5.172, -0.098)**	✓	✓	**0.0420***
PA Compliance (mL/mmHg)	**0.22 (0.009, 0.423)**	✓	✓	**0.0410***
RV Systolic Pressure (mmHg)	-8.10 (-13.877, -2.317)	✓	✓	0.0067*
PA Systolic Pressure (mmHg)	-6.98 (-12.774, -1.187)	✓	✓	0.0189*
PA Diastolic Pressure (mmHg)	-3.43 (-6.211, -0.643)	✓	✓	0.0165*
RV Fractional Area Change	2.62 (-1.405, 6.652)		✓	0.1983
PVR index (dyne*s/cm^5/m^2)	-160.42 (-333.970, 13.138)		✓	0.0695
mRAP (mmHg)	-0.99 (-2.350, 0.367)		✓	0.1503
Stroke Volume Index (mL/m^2)	2.19 (-0.917, 5.299)		✓	0.1644
Cardiac Index (L/min/m^2)	0.13 (-0.100, 0.359)		✓	0.2658

* $p \leq 0.05$.
Abbreviations: mRAP, mean right atrial pressure; PA, pulmonary artery; PVR, pulmonary vascular resistance; RV, right ventricle; LS, least squares; RHC, right heart catheterization; ECHO, echocardiography.
Source: Data on file.

The Majority of Patients Receiving Seralutinib Demonstrated an Improvement in REVEAL 2.0 Risk Score at Week 24



1-point improvement in REVEAL 2.0 Risk Score at baseline associated with[1]:

- **23% reduction in relative risk of death**
- **20% reduction in relative risk of clinical worsening**

Seralutinib patients have 2.45 times the odds of achieving a REVEAL 2.0 Risk Score improvement compared to placebo patients

30 of 39 seralutinib patients improved or maintained baseline REVEAL 2.0 Risk Score

Post hoc analysis. Odds ratio, 95% CI, and p-value from a stratified Cochran-Mantel-Haenszel chi-square test of improvement (yes vs. no).
1) A 1-point improvement in REVEAL 2.0 Risk Score (RRS) at PATENT-1 baseline was associated with a 23% reduction in the relative risk of death and a 20% reduction in the relative risk of clinical worsening in PATENT-2. Similarly, a 1-point improvement in RRS 2.0 at PATENT-1 Week 12 was associated with a 26% reduction in the relative risk of death and a 23% reduction in the relative risk of clinical worsening in PATENT-2. Source: https://doi.org/10.1016/j.ijcard.2021.03.034
Source: Data on file.

Safety and Tolerability

Top AEs From Imatinib IMPRES Study Not Observed at High Incidence in TORREY

Preferred Term [a]	IMPRES Study (Phase 3) Imatinib		TORREY Study (Phase 2) Seralutinib	
	Placebo (N=98)	Imatinib (N=103)	Placebo (N=42)	Seralutinib (N=44)
Nausea	23 (24)	57 (55)	6 (14)	5 (11)
Peripheral edema [b]	20 (20)	45 (44)	1 (2)	2 (5)
Diarrhea	19 (19)	36 (35)	3 (7)	6 (14)
Vomiting	10 (10)	31 (30)	3 (7)	2 (5)
Periorbital edema [c]	7 (7)	30 (29)	0 (0)	1 (2)
Dyspnea	13 (13)	19 (18)	5 (12)	4 (9)
Hypokalemia	3 (3)	16 (16)	1 (2)	2 (5)
Anemia	3 (3)	14 (14)	0 (0)	1 (2)
Face edema [d]	1 (1)	10 (10)	0 (0)	1 (2)
Muscle spasms	2 (2)	10 (10)	0 (0)	1 (2)

Abbreviations: AE: adverse event; MedDRA, Medical Dictionary for Regulatory Activities; PT, preferred term.
Note: AEs in IMPRES with an incidence ≥ 10% in Imatinib and ≥5% higher in Imatinib than Placebo are summarized for both IMPRES and TORREY.
Note: The above tables are for illustrative purposes only and are not a head-to-head comparison. Differences exist between study designs and methodologies, and caution should be exercised when comparing data across studies.
[a] Coded using MedDRA (v 24.0 in TORREY).
[b] Includes AE PTs of oedema, oedema peripheral, and peripheral swelling in TORREY.
[c] Includes AE PT of periorbital edema in IMPRES and AE PT of periorbital swelling in TORREY.
[d] Includes AE PT of face edema in IMPRES and AE PT of swelling face in TORREY.
Source: Data on file.

Incidence of TEAEs by Preferred Term: ≥ 5% in Seralutinib (Safety Population)

Preferred Term[a]	Placebo (N=42)	Seralutinib (N=44)
Number of subjects with a TEAE	36 (85.7)	41 (93.2)
Cough	16 (38.1)	19 (43.2)
COVID-19	7 (16.7)	6 (13.6)
Diarrhea	3 (7.1)	6 (13.6)
Headache	8 (19.0)	6 (13.6)
Dizziness	2 (4.8)	5 (11.4)
Fatigue	3 (7.1)	5 (11.4)
Nausea	6 (14.3)	5 (11.4)
Dyspnea	5 (11.9)	4 (9.1)
Nightmare	1 (2.4)	4 (9.1)
Abdominal pain lower	0	3 (6.8)
Arthralgia	1 (2.4)	3 (6.8)
Back pain	2 (4.8)	3 (6.8)
Chest discomfort	1 (2.4)	3 (6.8)
Nasal congestion	1 (2.4)	3 (6.8)
Nasopharyngitis	0	3 (6.8)
Rash	1 (2.4)	3 (6.8)
Throat irritation	0	3 (6.8)

All TEAEs in the table above were mild or moderate in severity.

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
[a] Coded using MedDRA v 24.0
Source: Data on file.

Incidence of Adverse Events Leading to Treatment Discontinuation (Safety Population)

Preferred Term[a]	Placebo (N=42)	Seralutinib (N=44)
Number of subjects with a TEAE leading to treatment discontinuation	1 (2.4)	6 (13.6)
Abdominal pain lower	0	1 (2.3)
Cough	0	1 (2.3)
Dry mouth	0	1 (2.3)
Haemoptysis	0	1 (2.3)
Alanine aminotransferase increased	0	1 (2.3)^
Aspartate aminotransferase increased	0	1 (2.3)^
Transaminases increased	0	1 (2.3)
Liver function test abnormal	1 (2.4)	0

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
[a] Coded using MedDRA v 24.0
^ Events occurred in same patient.
Source: Data on file.

Summary of TORREY Topline Results

Summary of Topline Results

- ✓ Primary endpoint met with concordant statistically significant and directional improvements from baseline across multiple endpoints, including hemodynamics, NT-proBNP, and right heart structure and function
- ✓ Drug characteristics, limited systemic PK, and route of administration led to the avoidance of safety/tolerability issues seen with systemic imatinib administration
- ✓ 6MWD improvement in more severe patient groups provides clear path forward for Phase 3 development program in PAH
- ✓ Statistically significant study in PAH and strong mechanistic rationale support development in Group 3 PH

Acknowledgements

We thank all patients, their families, and all the TORREY study investigators who participated in the trial

Next Steps

- 1H:23 – Complete End of Phase 2 Regulatory Interactions
- 2H:23 – Commence Global Registrational Phase 3 Program in PAH
- 2H:23-1H:24 – Commence Development Program in WHO Group 3 PH

Participants for Q&A Session

Gossamer Bio	
Faheem Hasnain	Co-Founder, Chairman, & Chief Executive Officer
Richard Aranda, MD	Chief Medical Officer
Robert Roscigno, PhD	VP, Clinical Development
Larry Zisman, MD FACC	Sr Dir, Clinical Development
Ed Parsley, DO	Consultant Pulmonologist
Matt Cravets	SVP, Biometrics
Laura Carter, PhD	Chief Scientific Officer
Caryn Peterson	EVP, Regulatory Affairs
Bryan Giraudo	COO & CFO

Guest Speakers

Ardeschir Ghofrani, MD*
Professor of Pulmonary Vascular Research, Justus Liebig University; Head of the Pulmonary Hypertension Division, University Hospital Giessen

Raymond Benza, MD*
Professor of Medicine, Division of Cardiovascular Medicine, The Ohio State University

*Drs. Ghofrani and Benza are investigators in the TORREY Study and are paid consultants to Gossamer.