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

FORM 8-K

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

Date of Report (Date of earliest event reported): September 12, 2017

FibroGen, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36740**	**77-0357827**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

FibroGen, Inc.
409 Illinois Street
San Francisco, CA 94158
(Address of principal executive offices, including zip code)

(415) 978-1200
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 September 12, 2017, FibroGen, Inc. presented currently available data from the company's Phase 2 randomized, double-blind, controlled study in patients with idiopathic pulmonary fibrosis (IPF) in an oral presentation by Luca Richeldi, M.D., Ph.D., Head of the Division of Pulmonary Medicine at Agostino Gemelli University Hospital of the Catholic University of the Sacred Heart in Rome, Italy. The presentation was given at the European Respiratory Society (ERS) International Congress 2017 in Milan, Italy.

A copy of such presentation, entitled "PRAISE, a randomized, placebo-controlled, double-blind Phase 2 clinical trial of pamrevlumab (FG-3019) in IPF patients," is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	FibroGen, Inc. presentation dated September 12, 2017, entitled "PRAISE, a randomized, placebo-controlled, double-blind Phase 2 clinical trial of pamrevlumab (FG-3019) in IPF patients."

SIGNATURES

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

Dated: September 12, 2017

FIBROGEN, INC.

By: /s/ Michael Lowenstein
Michael Lowenstein
Chief Legal Counsel

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	FibroGen, Inc. presentation dated September 12, 2017, entitled “PRAISE, a randomized, placebo-controlled, double-blind Phase 2 clinical trial of pamrevlumab (FG-3019) in IPF patients.”

Exhibit 99.1

The PRAISE Study

A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Pamrevlumab (FG-3019) in Patients with Idiopathic Pulmonary Fibrosis

FIBROGEN STUDY#: FGCL-3019-067
ClinicalTrials.gov ID#: NCT01890265

Prof. Luca Richeldi, MD
Policlinico A. Gemelli, Catholic University, Rome

PRAISE Background

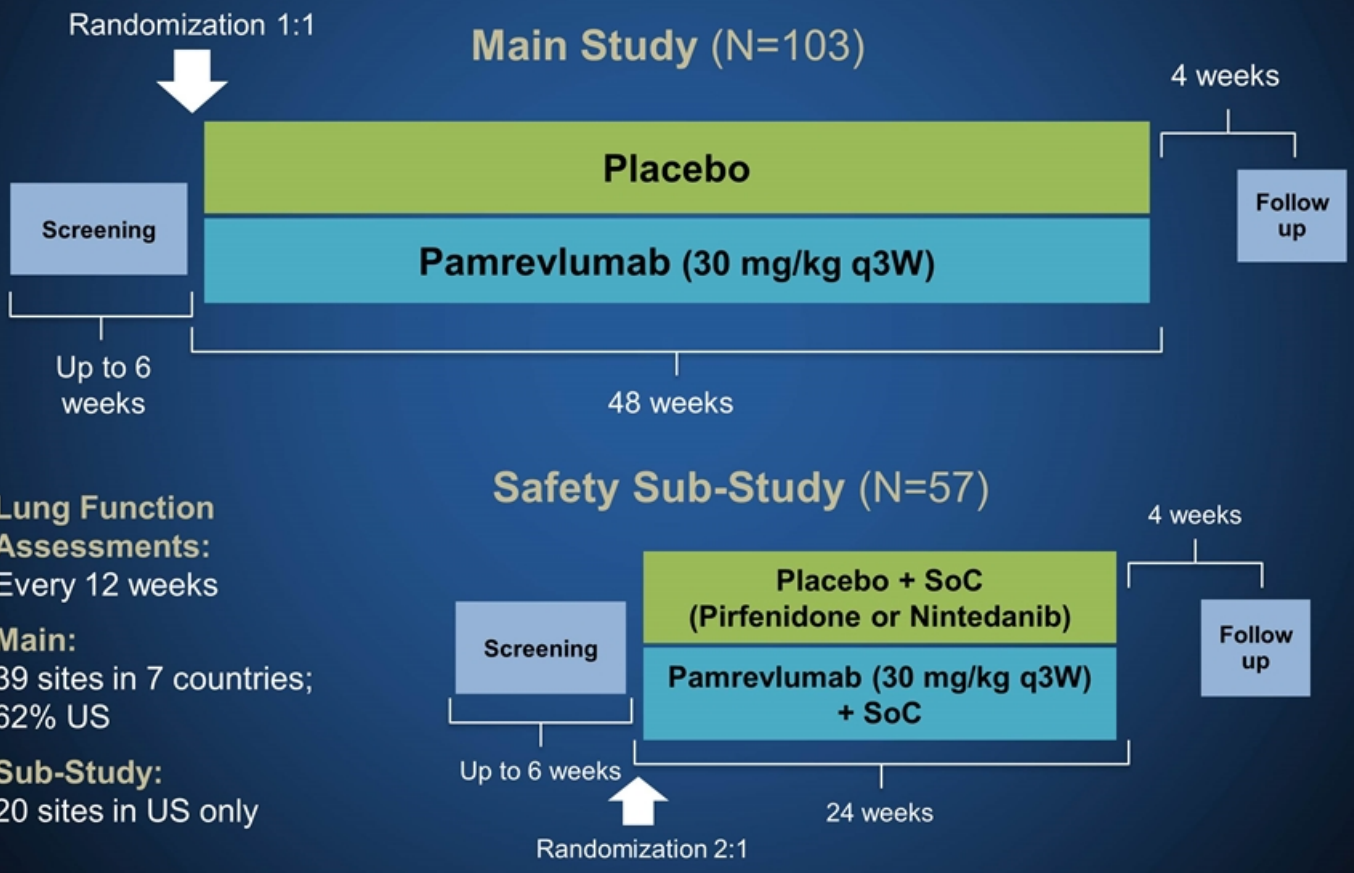
Pamrevlumab (FG-3019)

- A Human MAb Targeting CTGF
- Preclinical Data Supportive of Reversal of the Process of Fibrosis[1]
  - Decline in lung density over 8 weeks of therapeutic administration in a mouse Radiation-Induced Lung Fibrosis (RILF) model with durable effects after treatment cessation
  - Reversal of histologic lung remodeling and rapid change in biology of the remodeling lung by gene expression analysis
  - Repeat RILF testing with current SoC and combination therapy shows superior results for pamrevlumab in monotherapy (ERS Poster PA908)
- FGCL-3019-049 Open-Label Study[2]
  - 2.7% mean decline in %-predicted FVC at W48
  - Correlation between lung function and lung fibrosis
  - Pamrevlumab was well tolerated

1. Bickelhaupt S., JNCI Natl Cancer Inst, 2017. 2. Raghu G., Eur. Respir. Journal 2016; 47: 1481-1491

PRAISE Study Design

Randomized, Double-Blind, Placebo-Controlled



Lung Function Assessments:
Every 12 weeks

Main:
39 sites in 7 countries;
62% US

Sub-Study:
20 sites in US only

PRAISE Study Design

Eligibility

- **Age:** 40–80 years
- **Diagnosis** of IPF as per International Guidelines*
  - Definite UIP, or
  - Possible UIP+SLB

  Additionally, High Resolution Computerized Tomography should confirm:
  - ≥10% and <50% Fibrosis
  - <25% Honeycombing
- **FVC:** ≥55% percent of predicted
- **DL_{CO}:** ≥30% percent of predicted
- **FEV_1/FVC Ratio:** ≥0.70
- **Centralized Assessments:** Spirometry, Safety Labs

* Raghu G.,ATS/ERS/JRS/ALAT Idiopathic Pulmonary Fibrosis Diagnosis Guidelines, 2011

PRAISE Study Population

Subjects Screened (n)	214		
Subjects Randomized (n)	103 (Pamrevlumab=50; Placebo=53)		
Main Reasons for Screen Failures*:	Overall	US	Ex-US
- Non-qualifying FVC	34%	10%	24%
- Not meeting UIP criteria	26%	14%	12%
- Non-qualifying DIco	18%	9%	9%
- PI judgment	10%	2%	8%
- ≥10-50% fibrosis; <25%HC	7%	4%	3%
- Non-qualifying FEV1/FVC ratio	7%	3%	4%
- Non-qualifying labs	7%	5%	1%

*(Subjects may meet more than 1 reason for screening failure)

PRAISE Demographics and Baseline Characteristics, Safety Population

Variable*	Pamrevlumab (N=50)	Placebo (N=53)
Age (years)	68.3 ±7.05	68.4 ±7.20
Male Gender, n (%)	33 (66.0)	43 (81.1)
Race White, n (%)	41 (82.0)	44 (83.0)
Weight (Kg)	80.16 ±17.427	86.86 ±17.060
FVC (% predicted)	74.46 ±11.886	73.13 ±11.146
FEV_1/FVC ratio	0.812 ±0.0646	0.795 ±0.0524
DL_{co} (%-predicted, HB-cor.)	52.92 ±15.286	53.84 ±12.217
Time Since IPF Dx (yrs)	1.13 ±0.994	1.48 ±1.146
Former Smoker, n (%)	27 (54.0)	34 (64.2)
HRCT "Definite UIP", n (%)	37 (74.0)	29 (54.7)
HRCT "Possible UIP"+SLB, n (%)	11 (22.0)	22 (41.5)

*Data are presented as mean ± SD unless otherwise specified

Source: t-14-1-dm-saf; t-14-1-4-1-pft-saf

PRAISE Demographics and Baseline Characteristics, Safety Population (cont.)

Variable*	Pamrevlumab (N=50)	Placebo (N=53)
GAP Stage I / II / III (%)	46 / 48 / 6	45 / 51 / 4
GAP Score: mean ± SD	3.6 ± 1.34	3.6 ± 1.24
Enrollment by Country (%)		
U.S.	58.0	66.0
India	14.0	9.4
New Zealand	8.0	11.3
South Africa	8.0	9.4
Bulgaria	6.0	1.9
Australia	6.0	0.0
Canada	0.0	1.9

*Data are presented as mean ± SD unless otherwise specified

Source: t-14-1-4-2-blgap-saf ; t-14-1-1-enroll-rand

Safety Overview

Treatment Emergent Adverse Events*

Patients, n (%)	Pamrevlumab (N=50)	Placebo (N=53)
Any Adverse Event	48 (96.0)	52 (98.1)
Grade 3	10 (20.0)	8 (15.1)
Grade 4	1 (2.0)	2 (3.8)
Any Serious Adverse Event	12 (24.0)	8 (15.1)
All Reported Deaths	3 (6.0)	6 (11.3)
Any TEAE Leading to Treatment D/C	10 (20.0)	10 (18.9)
Serious TEAE Leading to Treatment D/C	3 (6.0)	7 (13.2)
Any Infusion-Associated Adverse Events	20 (40.0)	14 (26.4)

*Including all adverse events that occurred from first dose to 28 days post last dose

Source: t-14-3-1-teae-sum-saf

Most Common Treatment Emergent Adverse Events*

Patients, n (%)	Pamrevlumab (N=50)	Placebo (N=53)
Respiratory Tract Infection	15 (30.0)	11 (20.8)
Cough	14 (28.0)	23 (43.4)
Dyspnea	14 (28.0)	11 (20.8)
Idiopathic Pulmonary Fibrosis	10 (20.0)	9 (17.0)
Fatigue	10 (20.0)	4 (7.5)
Urinary Tract Infection	10 (20.0)	4 (7.5)
Nasopharyngitis	9 (18.0)	5 (9.4)
Sinusitis	8 (16.0)	8 (15.1)
Diarrhoea	8 (16.0)	4 (7.5)
Nausea	7 (14.0)	7 (13.2)
Headache	4 (8.0)	6 (11.3)
Bronchitis	2 (4.0)	6 (11.3)

*Occurring in >10% of patients in either group

Source: t-14-3-1-teae-inc10-saf + t-14-3-1-teae-saf

TESAEs* were Infrequent During the Study and Mostly Respiratory-Related

Patients, n (%)	Pamrevlumab (N=50)	Placebo (N=53)
Interstitial Lung Disease	2 (4.0)	0
Pulmonary Embolism	2 (4.0)	0
Cardiac Arrest	0	2 (3.8)
Idiopathic Pulmonary Fibrosis	0	4 (7.5)

Infusion-Associated TEAEs* Show Pamrevlumab Infusions are Generally Well Tolerated

Patients, n (%)	Pamrevlumab (N=50)	Placebo (N=53)
Nausea	3 (6.0)	5 (9.4)
Fatigue	3 (6.0)	1 (1.9)
Headache	3 (6.0)	3 (5.7)
Flushing	3 (6.0)	3 (5.7)
Hypertension	3 (6.0)	1 (1.9)
Dizziness	2 (4.0)	0
Depression	0	2 (3.8)

- All were mild to moderate in severity (none were serious AEs)
- Did not lead to study drug or study discontinuations

*Occurring in at Least 2 Subjects in either group

Source: t-14-3-2-tesae-saf; t-14-3-1-teae-ifurel-saf

All-Cause Mortality Rate

PRAISE vs GAP[1]

		Full Study (N=103)		Pamrevlumab Arm (N=50)		Placebo Arm (N=53)	
Stage	**1-year Risk**	**Number Subjects**	**Expected Number of Deaths**	**Number Subjects**	**Expected Number of Deaths**	**Number Subjects**	**Expected Number of Deaths**
Stage I	5.6%	47	2.6	23	1.3	24	1.3
Stage II	16.2%	51	8.3	24	3.9	27	4.4
Stage III	39.2%	5	2.0	3	1.2	2	0.8
Overall		103	**12.9**	50	**6.4**	53	**6.5**
Actual Deaths in PRAISE			**9**		**3**		**6**
Actual vs Expected Deaths				**47.0 %**		**92.3%**	

Deaths by Stages: Pamrevlumab arm: 2 Stage II; 1 Stage III. / Placebo arm: 2 Stage I; 3 Stage II; 1 Stage III

Relative Reduction vs Placebo = 51%

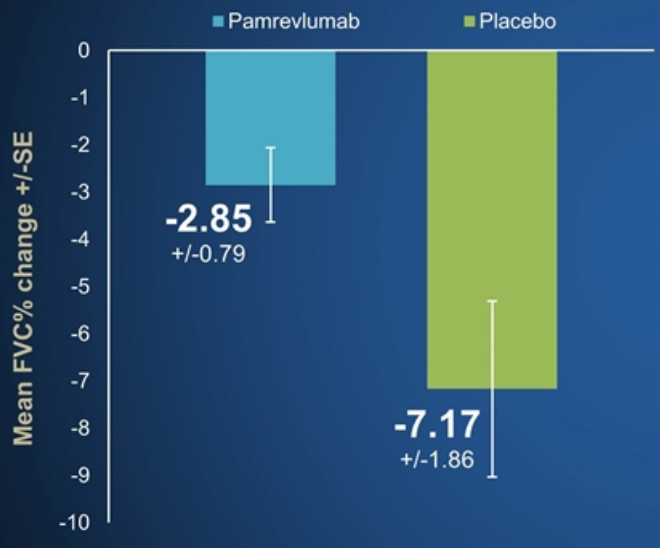
(Relative Reduction vs Placebo for Pooled Phase 2; Study 049+PRAISE = 65%)

1. Ley B. et al. Ann Intern Med. 2012.
Source: t-14-1-4-2-blgap-saf / l-16-2-4-4-blgap-rand

Efficacy Analysis, Primary Endpoint*; Mean Change from BL at Week 48 in FVC

Random Coefficients Model (Linear Slope method)

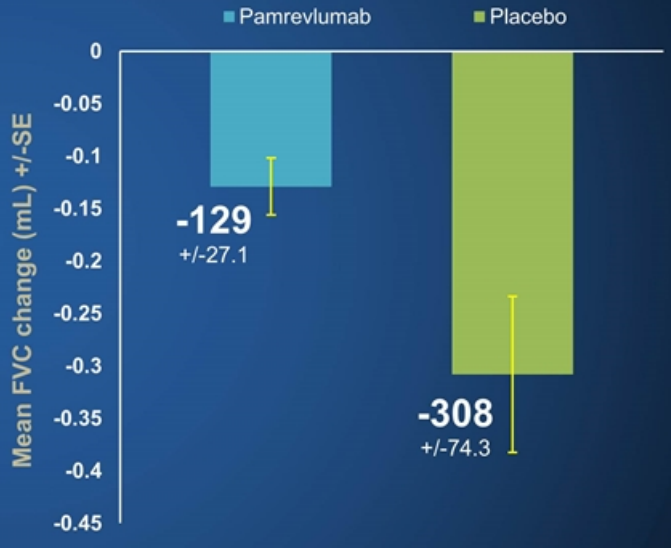
*FVC%-Predicted



p-value = 0.0331

FVC%-Predicted Difference: 4.33%
Relative Difference: 60%

FVC (mL)

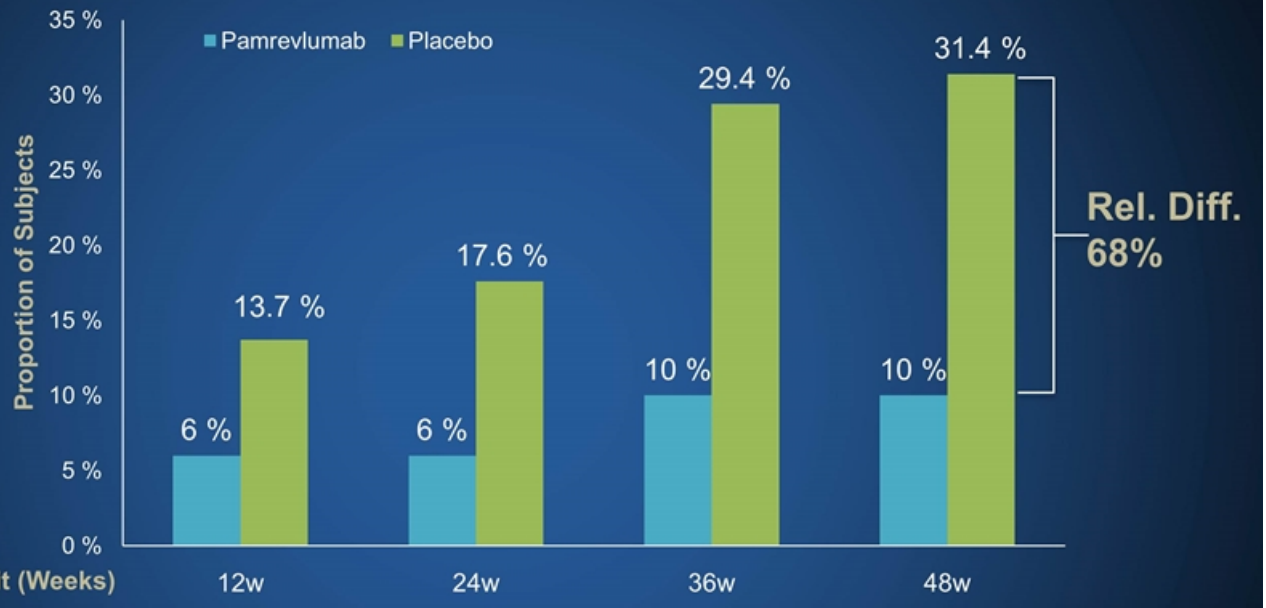


p-value = 0.0249

Absolute FVC Difference: 178mL
Relative Difference: 58%

Source: t-14-2-1-1n-fvcpp-saf.sas t-14-2-1-11q-fvc-saf.sas

Proportion of Subjects with FVC%-Predicted Decline ≥10% or Death by Visit. Logistic Regression Model

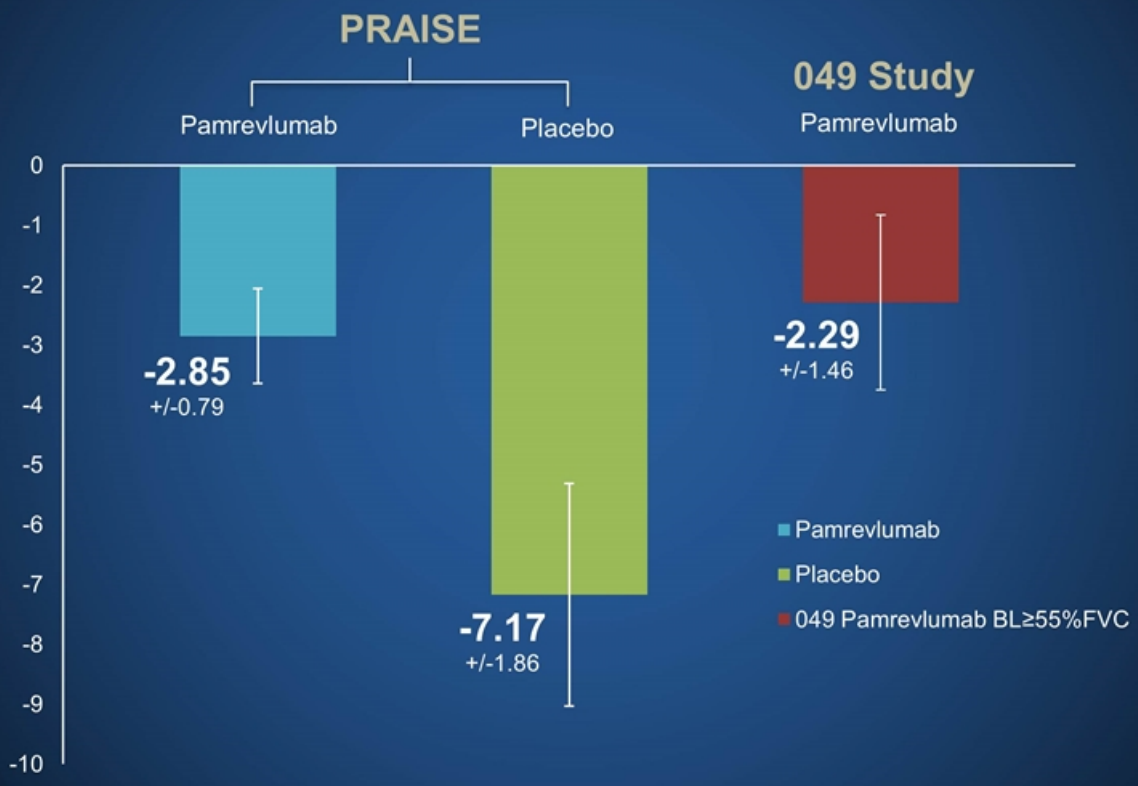


Visit (Weeks)	12w	24w	36w	48w
P-Value*	0.1235	0.0527	0.0172	0.0103
Pamrevlumab, n (%)	3 (6.0%)	3 (6.0%)	5 (10.0%)	5 (10.0%)
Placebo, n (%)	7 (13.7%)	9 (17.6%)	15 (29.4%)	16 (31.4%)
Relative Diff.	-56%	-66%	-66%	-68%

Source: t-14-2-1-2-fvcpp-prop-itt\ f-14-2-1-2-fvcpp-itt

FVC%-Predicted Change From BL at W48

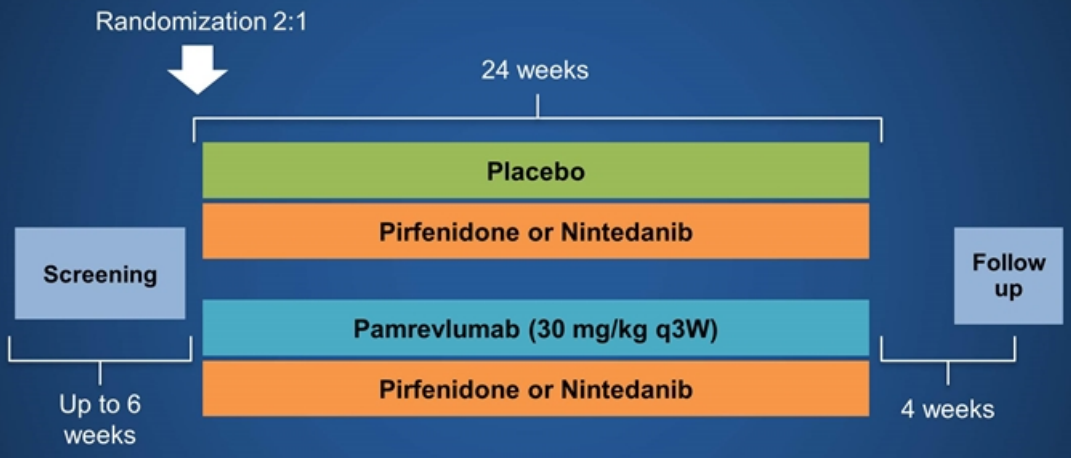
Consistency with Prior 049 Phase 2 Open-Label Study Results*



*Both studies analyzed according to Linear Slope method. Study 049 with subjects BL FVC≥55% and treated with 30mg/Kg dose (N=32); FVC%-p change from BL = 2.33% for 30mg/Kg+15mg/Kg doses (N=69)

PRAISE Combination Safety Sub-Study

Randomized, Double-Blind, Placebo-Controlled Trial with SoC Background Medication



- At least 3 months on stable dose of pirfenidone or nintedanib
- Total # of pamrevlumab (or matching placebo) doses = 8
  - First 2 doses at 15 mg/kg, remaining doses at 30 mg/kg
- 20 sites in U.S. only

Safety Sub-Study

Demographics and Baseline Characteristics

	Pirfenidone Group N=36		Nintedanib Group N=21	
Variable*	**Pam.+ Pirf.** (N=24)	**Pirf.** (N=12)	**Pam.+ Nint.** (N=15)	**Nint.** (N=6)
Age (years)	68.6 ± 6.27	68.4 ± 5.50	71.1 ± 7.32	65.2 ± 4.62
Male Gender, n (%)	17 (70.8)	8 (66.7)	13 (86.7)	3 (50.0)
Race White, n (%)	24 (100.0)	12 (100.0)	15 (100.0)	6 (100.0)
FVC (% predicted)	74.57 ± 15.764	71.91 ± 13.758	73.31 ± 14.559	70.12 ± 13.561
FEV_1/FVC Ratio	0.813 ± 0.0543	0.825 ± 0.0608	0.793 ± 0.0436	0.814 ± 0.0576
DL_{co} (%-p, HB-cor.)	52.70 ± 15.089	48.56 ± 10.224	48.35 ± 12.495	40.59 ± 9.027
Time Since IPF Dx (yrs)	2.10 ± 1.223	1.93 ± 0.959	2.00 ± 0.757	1.73 ± 1.212
HRCT "Definite UIP", n (%)	16 (66.7)	7 (58.3)	9 (60.0)	3 (50.0)
HRCT "Possible UIP"+SLB n (%)	8 (33.3)	5 (41.7)	6 (40.0)	3 (50.0)
GAP Stage I / II / III (%)	41.7 / 54.2 / 4.2	41.7 / 50 / 8.3	26.7 / 66.7 / 6.7	66.7 / 16.7 / 16.7

*Data are presented as mean ± SD unless otherwise specified

Source: t-14-1-dm-saf\t-14-1-4-1-pft-saf\t-14-1-4-2-blgap-saf

Safety Sub-Study

Safety Summary of Treatment Emergent Adverse Events

	Pirfenidone Group N=36		Nintedanib Group N=21	
Patients, n (%)	**Pam.+ Pirf.** (N=24)	**Pirf.** (N=12)	**Pam.+ Nint.** (N=15)	**Nint.** (N=6)
Any TEAE	19 (79.2)	12 (100.0)	14 (93.3)	6 (100.0)
Grade 3	1 (4.2)	2 (16.7)	2 (13.3)	1 (16.7)
Grade 4	0	1 (8.3)	0	0
Any Serious TEAE	2 (8.3)	1 (8.3)	0	1 (16.7)
All Reported Deaths	1 (4.2)	0	0	0
Any TEAE Leading to Treatment D/C	2 (8.3)	0	0	0
Serious TEAE Leading to Treatment D/C	2 (8.3)	0	0	0
Any Infusion-Associated AE	5 (20.8)	6 (50.0)	4 (26.7)	1 (16.7)

Source: t-14-3-1-teae-sum-saf

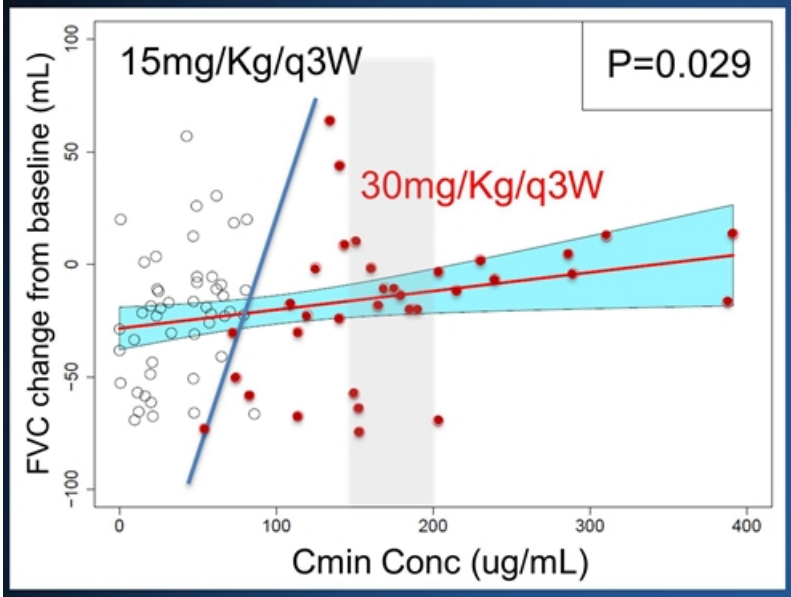
Safety Sub-Study

Most Common TEAEs in >10% of Patients

Patients, n (%)	Pam.+ Pirf. (N=24)	Pirf. (N=12)	Pam.+ Nint. (N=15)	Nint. (N=6)
Nasopharyngitis	5 (20.8)	3 (25.0)	4 (26.7)	0
Idiopathic Pulmonary Fibrosis	5 (20.8)	0	2 (13.3)	0
Cough	3 (12.5)	3 (25.0)	2 (13.3)	2 (33.3)
Fatigue	3 (12.5)	1 (8.3)	0	0
Respiratory Tract Infection	2 (8.3)	3 (25.0)	1 (6.7)	1 (16.7)
Dyspnea	2 (8.3)	2 (16.7)	3 (20.0)	2 (33.3)
Dizziness	1 (4.2)	2 (16.7)	0	0
Headache	1 (4.2)	2 (16.7)	0	0
Diarrhoea	1 (4.2)	2 (16.7)	3 (20.0)	1 (16.7)
Bronchitis	0	0	3 (20.0)	0
Sleep Apnea	0	0	2 (13.3)	0
GERD	0	0	1 (6.7)	1 (16.7)
Urinary Tract Infection	0	0	1 (6.7)	1 (16.7)
Decreased Appetite	0	0	1 (6.7)	1 (16.7)
Sinusitis	0	0	0	3 (50.0)
Nausea	0	0	0	2 (33.3)
Wound	0	0	0	1 (16.7)
Joint Swelling	0	0	0	1 (16.7)
Cholelithiasis	0	0	0	1 (16.7)
Lethargy	0	0	0	1 (16.7)

Source: t-14-3-1-teae-inc10-saf \ t-14-3-1-teae-saf

PK/PD Modeling Based on Study 049 Data Predicts Increased Efficacy with Higher Pamrevlumab Exposure



- Efficacy response (FVC) correlates with pamrevlumab exposure (Cmin)
- A Maximum Tolerated Dose with pamrevlumab has not yet been identified, which allows for further dose optimization in Phase 3

- In simulation, 30mg/Kg/2 weeks provides Cmin of 200ug/mL to ~80% of subjects

Simulated % Cmin > 200 ug/mL

Dose (mg/kg)	q3W	q2W
15	0 [0 - 1]	13 [7 - 18]
30	24 [17 - 31]	79 [72 - 86]
35	37 [29 - 47]	88 [82 - 94]
45	61 [52 - 70]	96 [92 - 99]

[5 – 95%ile] of 100 simulated trials using bootstrap parameters, N = 300 per cohort

The PRAISE Phase 2 Study
Summary/Conclusions

- Pamrevlumab shows significant benefit in lung function preservation vs placebo as measured by:
  - FVC%-predicted
  - FVC (mL)
  - FVC%-predicted decline of ≥10% or death
- Pamrevlumab was generally well tolerated either in monotherapy or in combination with SoC
- PRAISE Results are consistent with prior pamrevlumab Phase 2 IPF data
- Pamrevlumab warrants further clinical investigation in IPF

Acknowledgment to PRAISE Sites and Investigators

Thank you to all PRAISE TEAMS and our Study Collaborators

United States

• Anne Dixon, MD (Vermont Lung Center, Colchester, VT) • Catherine Markin, MD (Legacy Research Institute, Portland, OR) • Danielle D. Hosmer, MD (Legacy Research Institute, Portland, OR) • David Lederer, MD (Columbia University Medical Center, New York, NY) • Danielle Anti-Ozerkis, MD (Yale University, New Haven, CT) • Evan R. Fernandez Perez, MD (National Jewish Center, Denver, CO) • E. James Britt, MD (University of Maryland, Baltimore, MD) • Joao De Andrade, MD (University of Alabama at Birmingham, Birmingham, AL) • John Belperio, MD (David Geffen School of Medicine at UCLA, Los Angeles, CA) • Jonathan Ruzi, MD (Arizona Pulmonary Specialists, LTD, Scottsdale, AZ) • John Fitzgerald, MD (University of Texas Southwestern Medical Center, Dallas, TX) • Kevin Gibson, MD (University of Pittsburgh Medical Center, Pittsburgh, PA) • Krishna Thavarajah, MD (Henry Ford Medical Center, Detroit, MI) • Leslie Tolle, MD (Cleveland Clinic, Cleveland, OH) • Lisa Lancaster, MD (Vanderbilt University, Nashville, TN) • Mark Wencel, MD (Via Christi Clinic, Wichita, KS) • Mary Beth Scholand, MD (University of Utah – Lung Health Research, Salt Lake City, UT) • Mark Hamblin, MD (University of Kansas Medical Center, Kansas City, KS) • Murali Ramaswamy, MD (Pulmonlx LLC, Greensboro, NC) • Neil Ettinger, MD (St. Luke's Hospital, Chesterfield, MO) • Nishant Gupta, MD (University of Cincinnati, Cincinnati, OH) • Peter LaCamera, MD (Steward St. Elizabeth's Medical Center, Boston, MA) • Peter Andras Bercz, MD (Pensacola Research Consultants, Inc., Pensacola, FL) • Richard Enelow, MD (Dartmouth – Hitchcock Medical Center, Lebanon, NH) • Rafael Perez, MD (University of Louisville, Louisville, KY) • Rishi Raj, MD (Northwestern University, Chicago, IL) • Srihari Veeraraghavan, MD (Emory University, Atlanta, GA) • Sangeeta Bhorade, MD (Northwestern University, Chicago, IL) • Timothy Albertson, MD (UC Davis Medical Center, Sacramento, CA) • Thomas O'Brien, MD (Pulmonary Disease Specialist, PA d/b/a, PDS Research, Kissimmee, FL) • Yolanda Mageto, MD (Vermont Lung Center, Colchester, VT)

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• Anish Ambaram, MD (Life Mount Edgecombe Hospital, KwaZulu-Natal, South Africa) • Elvis Irusen, MD (Tygerberg Hospital Respiratory Research Unit, Western Cape, South Africa) • Heidi Siebert, MD (Into Research, Gauteng, South Africa)

Australia

• Elizabeth Veitch, MD (Concord Repatriation General Hospital, New South Wales, Australia) • Huw Davies, MD (Daw Park Repatriation Hospital, South Australia, Australia)

Bulgaria

• Natalia Stoeva, MD (MHAT 'Tokuda Hospital Sofia', AD, Department of Pulmonology, Sofia, Bulgaria)

Canada

• Nadim Srour, MD (Université de Sherbrooke/Hôpital Charles LeMoyne, Greenfield Park, QC)