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): November 16, 2020

CORBUS PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37348**	**46-4348039**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

500 River Ridge Drive, Norwood, MA	**02062**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code: **(617) 963-0100**

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 (see General Instruction 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**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	CRBP	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1 933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01. Regulation FD Disclosure.

Corbus Pharmaceuticals Holdings, Inc. (the "Company") is using the slides attached hereto as Exhibit 99.1 to this Current Report on Form 8-K in connection with management presentations to describe additional data from its RESOLVE-1 Phase 3 study of lenabasum for the treatment of systemic sclerosis.

The information in this Current Report on Form 8-K under Item7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

Exhibit No.	Description
99.1	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Dated: November 16, 2020

By: */s/ Yuval Cohen*
Name: Yuval Cohen
Title: Chief Executive Officer

Exhibit 99.1

CORBUS™
PHARMACEUTICALS

Pioneering transformative medicines that target the endocannabinoid system

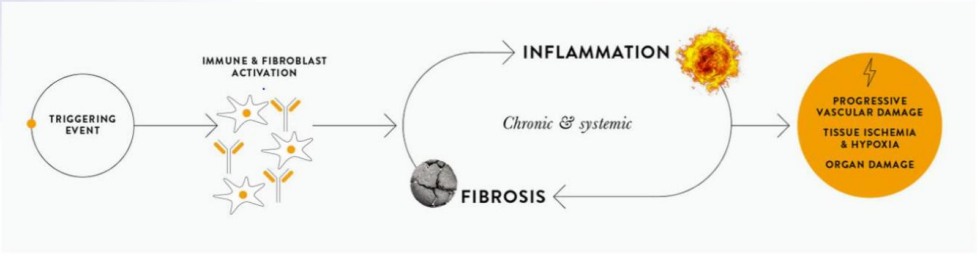
RESOLVE-1 Phase 3 Study of Lenabasum in Systemic Sclerosis

@corbuspharma

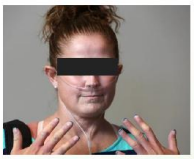
NASDAQ: CRBP
www.corbuspharma.com

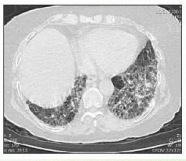
Systemic Sclerosis: The Unmet Need

Systemic sclerosis is a rare, debilitating and life-threatening autoimmune disease characterized by inflammation & fibrosis



~200,000
people with SSc in US, EU and Japan[1]



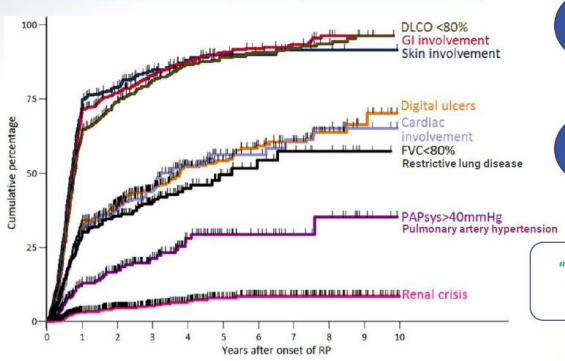


Interstitial Lung Disease in SSc

1. Furst. J Rheumatol. 2012, Aurore Bergamasco et al., Clin Epidemiol, 2019 & Health Advances, LLC Corbus Commercial Assessment
Patient Images (bottom) Provided by the Scleroderma Foundation;

Systemic sclerosis has among the highest mortality of systemic autoimmune diseases, driven primarily by its deleterious effects on major organs

Incident organ involvement in SSc from onset of Raynaud's phenomenon



Source: Jaeger VK, et al. PLoS One 2016. doi:10.1371/journal.pone.0163894.g003
Abbreviations: RP, Raynaud's Phenomenon; DLCO, single breath diffusing capacity for monoxide; FVC, forced vital capacity; PAPsys, systolic pulmonary artery pressure as estimated by echocardiography

4 x Patients with SSc have four times (4x) greater risk of death than their healthy counterparts[1]

~11 years Median 11 years of survival[2]

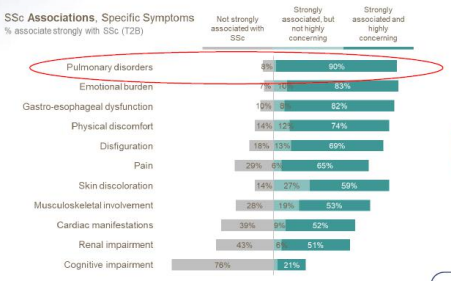
"Treatment for scleroderma is the number one unmet need in rheumatology today."

US Treatment Center Rheumatologist*

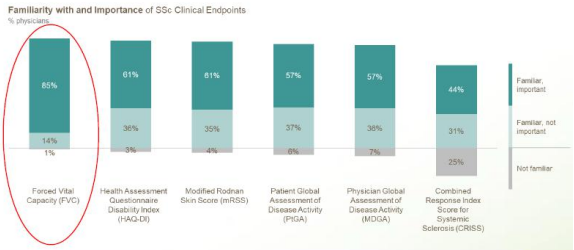
1. Hao et al., Arthritis & Rheumatology, 2017
2. Mayes et al., Arthritis & Rheumatism, 2003
* Quote from proprietary qualitative market research conducted in H2 2019 [n=20 U.S. Rheumatologists]

Physicians are most concerned with lung involvement in SSc

Rheumatologists rank pulmonary disorders as the most strongly associated and highly concerning of SSc specific symptoms…



...they are also most familiar with, and find most important, forced vital capacity (FVC) as an SSc endpoint



"How severe is the organ-system involvement, that is the crucial issue, GI and lung. Lung is the biggest concern."

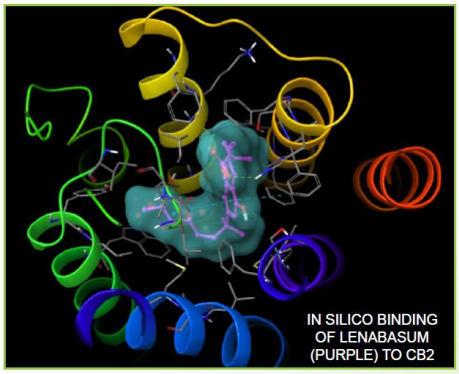
US Community Rheumatologist*

Source: Corbus SSc ATU Study, March 2020 (n = 100 US Rheumatologists)
* Quote from proprietary qualitative market research conducted in H2 2019 [n = 20 U.S. Rheumatologists]

Rationale for Lenabasum in Systemic Sclerosis

Lenabasum is a CB2 agonist designed to provide an alternative to immunosuppressive treatments for chronic inflammatory and fibrotic diseases

- Oral agonist of cannabinoid receptor type 2 (CB2), a GPCR that regulates inflammation and fibrosis
- Designed as a disease-modifying **alternative to immunosuppressive treatments** for chronic inflammatory and fibrotic diseases
- Has effects on immune cells and fibroblasts, both of which express CB2 when activated
- Reduces inflammatory cells and cytokines in tissue
- Reduces myofibroblasts and pro-fibrotic growth factors in tissue



IN SILICO BINDING OF LENABASUM (PURPLE) TO CB2

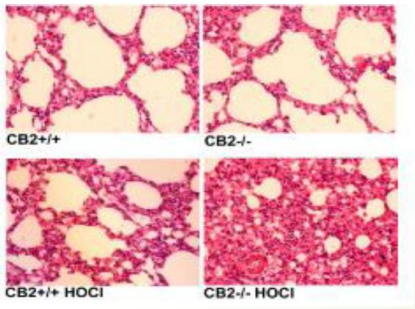
Animal model data provide link between CB2 and systemic sclerosis

Mice without CB2 (CB2-/- knock-out mice) develop excessive **lung and skin fibrosis** and **SSc-specific autoantibodies** (anti-DNA topoisomerase 1 antibodies) when their immune system is activated with hypochlorite (HOCl)[1].

Lung fibrosis is shown.

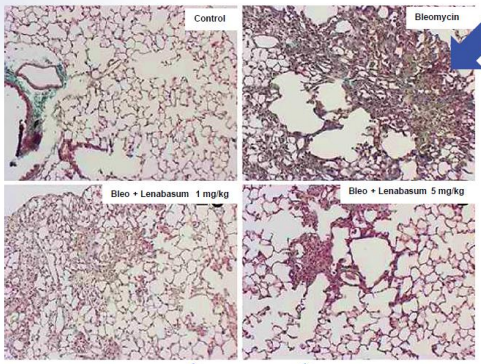
Servettaz et al. Am J Pathol 2010;177:187-96

Excessive lung fibrosis develops in mice without CB2



Excessive lung fibrosis in absence of CB2

Lenabasum reduced fibrosis in an animal model of SSc lung disease



Lenabasum inhibited lung fibrosis

Lung fibrosis induced with bleomycin

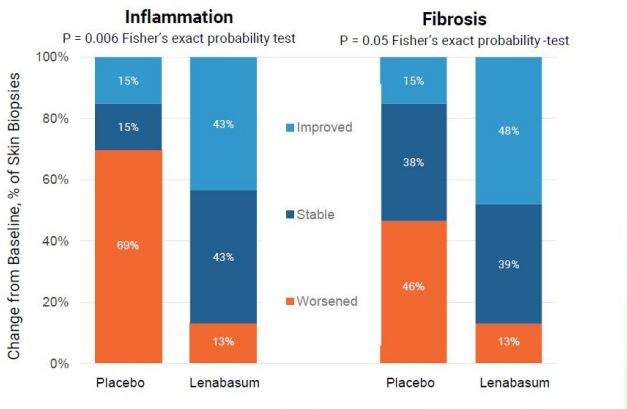
- Lung fibrosis is induced with bleomycin (bleomycin versus control)
- Lenabasum, whether started prophylactically before bleomycin or therapeutically 1 week after bleomycin, reduced lung inflammation and fibrosis
- Lung histology is shown for Day 14 post-bleomycin, when lenabasum was starting therapeutically at Day 8

Lucatelli, Respir Res. 2016;17:49

Phase 2 Biomarkers

Phase 2 | Lenabasum improved inflammation and fibrosis in skin biopsies from SSc patients in a Phase 2 study

More improvement or stability of histological findings of inflammation and fibrosis in paired skin biopsies after 12 weeks treatment with lenabasum versus placebo



Analyses are of paired skin biopsies at baseline and Week 12, N = 23 lenabasum and N = 13 placebo.

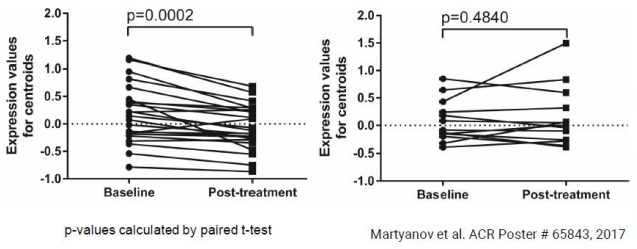
Phase 2 Biomarkers

Phase 2 | Lenabasum reduced expression of gene pathways involved in fibrosis in skin biopsies from SSc patients

Greater reduction in gene ontology pathways associated with inflammation and fibrosis in paired skin biopsies after 12 weeks treatment with lenabasum versus placebo.

Results are shown for the extracellular matrix organization gene ontology pathway

Extracellular Matrix Organization Pathway



p-values calculated by paired t-test

Martyanov et al. ACR Poster # 65843, 2017

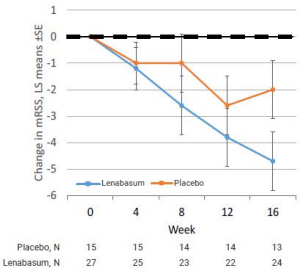
Analyses are of paired skin biopsies at baseline and Week 12, N = 23 lenabasum and N = 13 placebo.

Phase 2 Efficacy

Phase 2 | Lenabasum improved efficacy results in a 16-week Phase 2 study in SSc

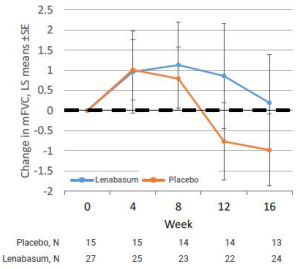
Greater numerical reduction in modified Rodnan skin score (mRSS), a measure of skin fibrosis, and forced vital capacity (FVC) percent predicted, a measure of lung function, after 12 weeks treatment with lenabasum versus placebo

Change in mRSS



Placebo, N	15	15	14	14	13
Lenabasum, N	27	25	23	22	24

Change in FVC, % predicted



Placebo, N	15	15	14	14	13
Lenabasum, N	27	25	23	22	24

RESOLVE-1 Phase 3 Study Design and Results

Phase 3 | Eligibility criteria and efficacy endpoints in the RESOLVE-1 Phase 3 study were similar to those in Phase 2

Phase 3 Design

- Double-blind, randomized, placebo-controlled, 52-week study of lenabasum in diffuse cutaneous SSc
- ACR CRISS at Week 52 was the primary efficacy endpoint
- Change in FVC % predicted was a secondary efficacy endpoint

Design

Primary endpoint: ACR-CRISS

365 subjects

52 weeks

76 sites in

1:1:1 dosing — 20 mg BID | 5 mg BID | Placebo

SECONDARY ENDPOINTS

- Change from baseline in mRSS
- Change from baseline in HAQ-DI
- Change from baseline in FVC % predicted

Orphan Drug Designation from FDA, EMA and PMDA
Fast Track status from FDA

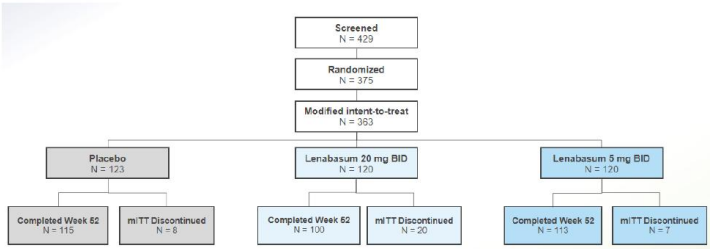
Eligibility

- Diffuse cutaneous SSc
- Disease duration ≤ 6 years. If 3-6 years, then mRSS ≥ 15
- Most background immunosuppressive therapies allowed if:
  - Stable for at least 8 weeks before Screening
  - Steroids not to exceed 10 mg prednisone per day or equivalent
- Decision to allow background immunosuppressive therapies was made to reflect current clinical practice

Phase 3 Disposition

Phase 3 | 90% of the modified intent-to-treat population completed the RESOLVE-1 Phase 3 study

Lower than anticipated drop-out rate of 9.6%



Modified intent-to-treat (mITT) population included subjects who received at least 1 dose of study drug and had at least 1 efficacy assessment after baseline.

Phase 3 | Baseline demographics in RESOLVE-1 were as expected

Phase 3 Baseline

- Many subjects were middle-aged, white, non-Hispanic females
- About 37% of subjects were from the United States

	Placebo N = 123	Lenabasum 5 mg N = 120	Lenabasum 20 mg N = 120
Age, years, mean (SD)	51.9 (12.38)	49.7 (13.51)	49.7 (12.87)
Female, %	74.0	73.3	80.0
Race, %			
White	71.5	66.7	70.0
Asian	21.1	20.0	20.0
Black	3.3	6.7	5.0
Hispanic, %	8.1	5.0	11.7
BMI (kg/m^2) (SD)	24.8 (5.27)	24.5 (4.96)	25.0 (5.61)
US, %	37.4	37.5	36.7
Canada/Europe/Israel/Australia, %	44.7	45.8	45.0
Asia (Japan and South Korea), %	17.9	16.7	18.3

Phase 3 | Baseline disease characteristics in RESOLVE-1 were as expected

Phase 3 Baseline

Subjects had moderate to severe disease despite frequent treatment with immunosuppressants

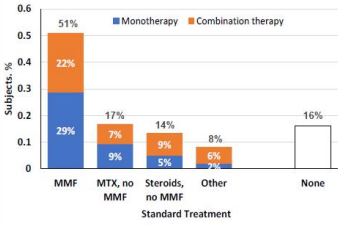
Characteristic (range)	Placebo N = 123	Lenabasum 5 mg N = 120	Lenabasum 20 mg N = 120
	N (%) or mean (SD)		
Disease duration, months	30.2 (16.84)	32.2 (17.62)	32.7 (19.94)
<= 3 years	66%	59%	61%
> 3 years	34%	41%	39%
Modified Rodnan Skin Score (0-51)	23.3 (8.68)	22.0 (7.35)	22.1 (8.55)
Physician Global Assessment (0-10)	5.6 (1.71)	5.4 (1.58)	5.3 (1.46)
Health Assessment Questionnaire (0-3)	1.16 (0.768)	1.07 (0.765)	1.12 (0.782)
Patient Global Assessment (0-10)	5.0 (2.10)	4.8 (2.16)	5.0 (2.10)
Forced Vital Capacity, % predicted	78.9 (15.23)	79.5 (16.13)	81.3 (18.8)
Immunosuppressive Use	84%	78%	89%

Phase 3 Background Meds

Phase 3 | The majority of subjects in RESOLVE-1 were receiving background treatment with the immunosuppressant mycophenolate

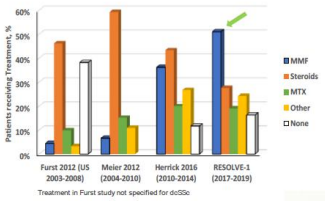
- 84% of RESOLVE-1 subjects were receiving stable doses of background immunosuppressive therapies (IST)
- Mycophenolate was the dominant IST
- Use of mycophenolate appears to be increasing in clinical practice

Background immunosuppressive therapy use in RESOLVE-1



- Only 16% were not receiving with background immunosuppressive therapies (IST)
- About half (51%) of subjects in RESOLVE-1 were on background mycophenolate

Increasing use of mycophenolate



Treatment in Furst study not specified for dcSSc

With time

- Fewer patients not receiving any IST
- **MMF may be becoming the dominant IST**
- Less steroid use

Phase 3 | Baseline immunosuppressant therapies appeared to influence efficacy outcomes in RESOLVE-1

Phase 3 IST

- Efficacy was much higher than expected in the placebo group
- Background IST appeared to cause the high efficacy in the placebo group, especially mycophenolate and other IST started within 2 years before baseline

Placebo group, Week 52

	N	ACR CRISS, median	Change in mRSS, mean	Change in FVC%, mean	Change in FVC, mL, mean
All placebo subjects[1]	113	0.894	-8.0	-1.2	-51
Any immunosuppressant therapy (IST)	97	0.936	-8.9	-1.0	-43
No IST	16	0.417	-2.3	-2.8	-97
Mycophenolate (MMF) ± any other IST	62	0.953	-10.1	0.1	-8
No MMF, any other IST	35	0.747	-6.8	-2.9	-107
MMF started ≤ 2 years before baseline	47	0.994	-11.6	1.3	31
MMF started > 2 years before baseline	15	0.652	-5.5	-3.6	-130
All non-MMF IST started ≤ 2 years before baseline, no MMF	24	0.931	-6.7	-1.4	-52
≥ 1 non-MMF IST started > 2 years before baseline, no MMF	11	0.301	-6.9	-6.1	-225
All IST started ≤ 2 years before baseline	71	0.962	-10.0	0.4	3
≥ 1 background IST started > 2 years before baseline; MMF must be > 2 years duration (established IST)	26	0.619	-6.1	-4.6	-170

- Higher ACR CRISS score is greater improvement
- Negative change in mRSS is improvement, positive change is worsening
- Positive change in FVC % predicted or mL is improvement, negative change is worsening

Per protocol population, completed study and study drug, LOCF for missing mRSS, FVC values

Phase 3 | There were no significant differences among treatment groups in primary efficacy outcome, ACR CRISS score, at Week 52

Phase 3 ACR CRISS

- ACR CRISS score was much higher than expected in the placebo group
- No additional efficacy discerned in lenabasum cohorts

	Lenabasum 20 mg BID N = 120	Lenabasum 5 mg BID N = 120	Placebo N = 123
Visit 11 (Week 52)			
n	100	113	115
Mean (SD)	0.5983 (0.43229)	0.5749 (0.42319)	0.6360 (0.42229)
Median (Q1, Q3)	0.8880 (0.0610, 0.9970)	0.8270 (0.0700, 0.9880)	0.8870 (0.0710, 0.9990)
p-value - Ranked Score, MMRM	0.4972	0.3486	

- Primary efficacy analysis compared lenabasum 20 mg BID vs placebo
- There were also no significant differences among treatment groups for the secondary efficacy outcomes

mITT population, primary efficacy analysis. MMRM with imputed values for missing core items, except LOCF for core items missing because of COVID-19. Table 14.2.1.1

Phase 3 ACR CRISS

Phase 3 | Few subjects in RESOLVE-1 had ACR CRISS Step 1 = 0 scores that indicate very bad heart, lung, or renal outcomes

Low numbers of subjects in RESOLVE-1 experienced very bad heart, lung, or renal outcomes, as measured using ACR CRISS Step 1 criteria

ACR CRISS Step 1 = 0 score indicates subject developed new significant, heart, lung, or kidney involvement, using pre-specified criteria

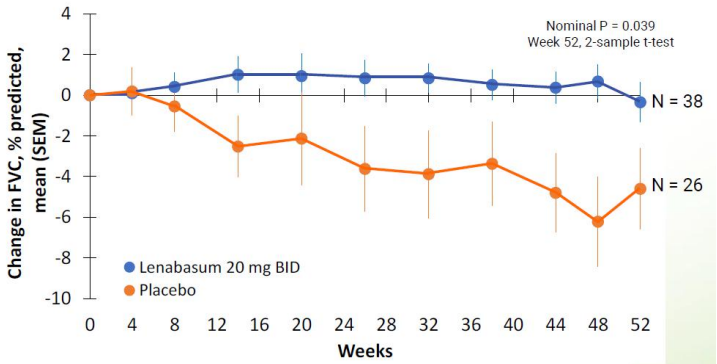
Step 1 Criteria	Placebo N = 123, n (%)	Lenabasum 5 mg BID N = 120, n (%)	Lenabasum 20 mg BID N = 120, n (%)
New renal crisis, hypertensive	1	-	-
New pulmonary artery hypertension	-	-	-
New congestive heart failure	-	1	1
New interstitial lung disease (ILD)	3	3	1
New ILD at ≥ 2 consecutive visits	3	1	-
Total	4 (3.3%)	4 (3.4%)	2 (1.7%)

Detailed criteria can be found in Khanna. Arthritis Rheumatol. 201;68:299-311

Phase 3 Efficacy

Phase 3 | Subjects treated with lenabasum 20 mg BID added to established IST (> 2 years duration) had stable **FVC % predicted**

Subjects treated with lenabasum 20 mg BID added to established immunosuppressant therapies (IST) had stable FVC % predicted over 1 year



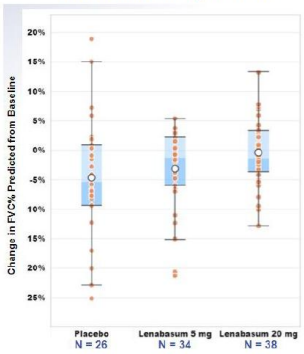
IST = immunosuppressant therapies. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration

Phase 3 Efficacy

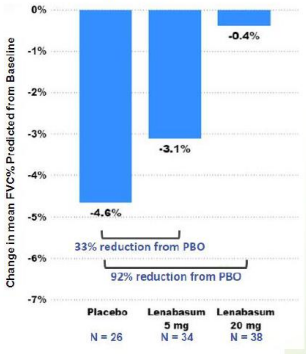
Phase 3 | Subjects treated with lenabasum 20 mg BID added to established IST had stable **FVC % predicted** over 1 year

Subjects had more stable lung function (FVC, % predicted) over 1 year when lenabasum 20 mg BID was added to established immunosuppressive therapies, compared to subjects treated with placebo

Change in FVC % predicted individual values, Week 52



Change in mean FVC % predicted, Week 52



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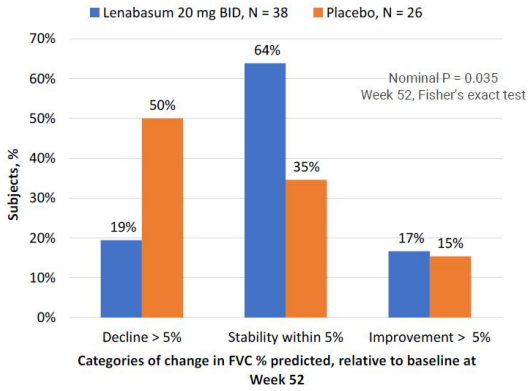
Phase 3 Efficacy

Phase 3 | Subjects treated with lenabasum 20 mg BID added to established IST had less decline and more stability in **FVC % predicted**

A lower proportion of subjects treated with lenabasum 20 mg BID added to established immunosuppressive therapies had worsening lung function and a higher proportion had stable lung function, compared to subjects treated with placebo

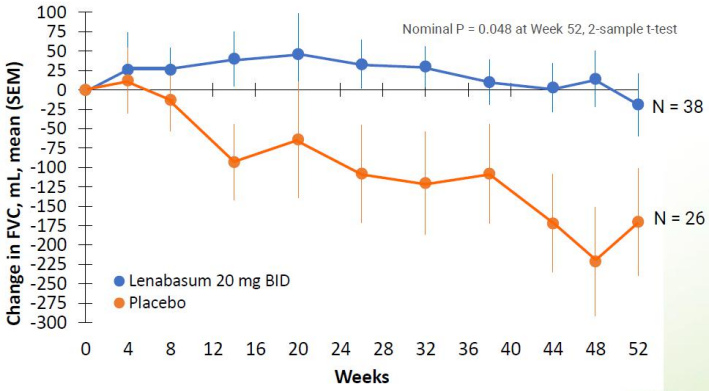


IST = immunosuppressant therapies. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration

Phase 3 Efficacy

Phase 3 | Subjects treated with lenabasum 20 mg BID added to established IST had stable **FVC mL** over 1 year

Subjects treated with lenabasum 20 mg BID added to established immunosuppressive therapies had stable FVC, mL over 1 year



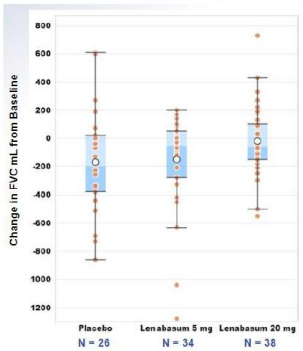
IST = immunosuppressant therapies. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration

Phase 3 Efficacy

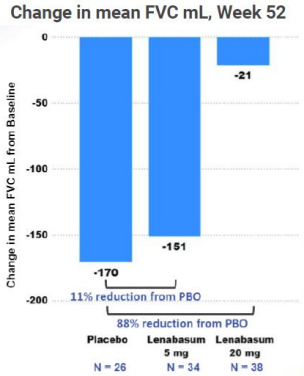
Phase 3 | Subjects treated with lenabasum 20 mg BID added to established IST had stable **FVC mL** over 1 year

Subjects had more stable lung function (FVC, mL) over 1 year when lenabasum 20 mg BID, rather than placebo, was added to established immunosuppressive therapies

Change in FVC mL individual values, Week 52



Change in mean FVC mL, Week 52



IST = immunosuppressant therapies. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration

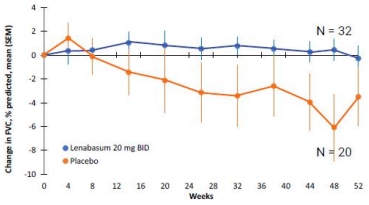
Phase 3 Efficacy

Phase 3 | **Subjects with ILD** treated with lenabasum 20 mg BID added to established IST also had stable **FVC % predicted** over 1 year

Subjects with interstitial lung disease treated with lenabasum 20 mg BID added to established immunosuppressive therapies had stable FVC, % predicted over 1 year

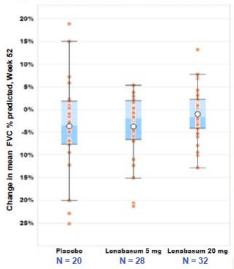
Interstitial lung disease (ILD) was defined as history of fibrosis on chest X-ray or computerized tomography of lungs or pattern of restrictive lung disease on spirometry including FVC < 80% predicted at baseline

Change in FVC % predicted over 1 year



Not statistically significant, Week 52

Change in FVC % predicted individual values, Week 52

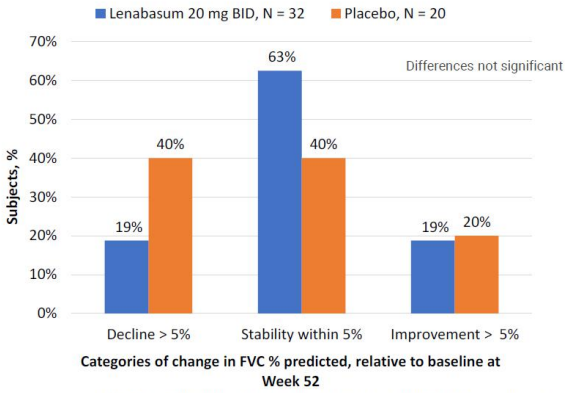


IST = immunosuppressant therapies. ILD = interstitial lung disease. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration

Phase 3 | **Subjects with ILD** treated with lenabasum 20 MG BID added to established IST had less worsening and more stability in **FVC % predicted**

Phase 3 Efficacy

Numerically lower proportions of subjects treated with lenabasum added to established IST had worsening lung function and a higher proportion had stable lung function, compared to subjects treated with placebo



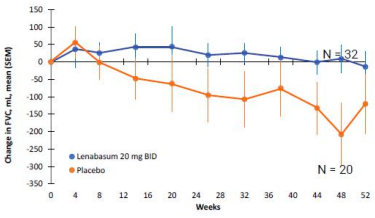
IST = immunosuppressant therapies. ILD defined as described in previous slide. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration.

Phase 3 Efficacy

Phase 3 | **Subjects with ILD** treated with lenabasum 20 mg BID added to established IST also had stable **FVC mL** over 1 year

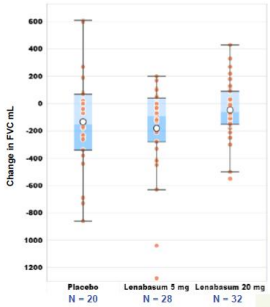
Subjects with interstitial lung disease treated with lenabasum 20 mg BID added to established immunosuppressive therapies had stable FVC, mL over 1 year

Change in FVC mL over 1 year



Not statistically significant, Week 52

Change in FVC mL individual values, Week 52



IST = immunosuppressant therapies. ILD defined as described in previous slide. Post-hoc analyses, per protocol population of subjects who completed study drug and Week 52, LOCF for any missing values. Subjects were receiving at least 1 background IST for greater than 2 years treatment duration at baseline, and any MMF treatment must be > 2 years duration.

Phase 3 | Efficacy Results in RESOLVE-1 at Week 52 in Subjects Receiving No Background Immunosuppressants

Phase 3 Baseline

- Greater improvement seen in multiple efficacy endpoints in subjects receiving lenabasum 20 mg BID compared to subjects receiving placebo, although small numbers of subjects in each group

Result	Placebo N = 15	Lenabasum 20 mg BID N = 10
ACR CRISS, median (IQR)	0.42 (0.895)	0.81 (0.836)
mRSS, mean (SE)	-2.3 (2.0)	-6.3 (1.3)
FVC % predicted, mean (SE)	-2.8 (1.6)	-2.3 (1.2)
HAQ-DI, mean (SE)	0.12 (0.074)	-0.06 (0.111)
MDGA, mean (SE)	-1.1 (0.41)	-1.6 (0.47)
PtGA, mean (SE)	-0.9 (0.59)	-3.3 (0.72)

Phase 3 Safety

Phase 3 | Lenabasum's safety profile remained favorable in RESOLVE-1

Lenabasum's safety profile was favorable, with fewer serious and severe AEs in lenabasum groups compared to placebo

Lenabasum was well-tolerated with no potentially or definitely-related TEAE leading to study drug discontinuation

Treatment-emergent Adverse Events (TEAE)	Placebo N = 123, n (%)	Lenabasum 5 mg N = 120, n (%)	Lenabasum 20 mg N = 120, n (%)
Any TEAE	106 (86.2)	110 (90.2)	110 (91.7)
Any Serious TEAE	18 (14.6)	10 (8.2)	11 (9.2)
Any TEAE by Maximum Severity			
Mild	44 (35.8)	47 (38.5)	55 (45.8)
Moderate	46 (37.4)	59 (48.4)	48 (40.0)
Severe	16 (13.0)	4 (3.3)	7 (5.8)
Any TEAE by Strongest Relationship			
Unrelated	41 (33.3)	35 (28.7)	36 (30.0)
Unlikely	30 (24.4)	34 (27.9)	27 (22.5)
Possible	33 (26.8)	36 (29.5)	42 (35.0)
Probable	2 (1.6)	5 (4.1)	4 (3.3)
Definite	0	0	1 (0.8)
Any TEAE Leading to Study Drug Discontinuation	7 (5.7)	2 (1.6)	5 (4.2)
Potentially Related TEAEs Leading to Study Drug Discontinuation	1 (0.8)	0	0
Any TEAE Leading to Death	1 (0.8)	0	1 (0.8)

Safety population of 365 subjects receiving at least 1 dose of study drug. Deaths during active treatment were unrelated to study drug. Death in the placebo group was from rapidly progressing SSc with respiratory and renal failure. Death in the lenabasum 20 mg group was from myocarditis leading to heart and respiratory failure.

Phase 3 Safety

Phase 3 | TEAEs occurring in at least 3% more of lenabasum 20 mg twice daily or placebo group, compared to the other group

Likely class effects of dizziness, dry mouth and somnolence occurred more frequently in lenabasum groups than placebo

No increase in neutropenia, opportunistic infections, or malignancies was seen to suggest immunosuppression

At least 3% more frequent in lenabasum 20 mg twice daily than placebo groups

System Organ Class	Placebo N=123, n (%)	Lenabasum 5 mg BID N=122, n (%)	Lenabasum 20 mg BID N=120, n (%)
Dizziness	6 (4.9%)	11 (9.0%)	22 (18.3%)
Dry mouth	2 (1.6%)	7 (5.7%)	6 (5.0%)
Somnolence	0	1 (0.8%)	5 (4.2%)
Nausea	13 (10.6%)	5 (4.1%)	17 (14.2%)
Vomiting	7 (5.7%)	7 (5.7%)	15 (12.5%)
UTI	6 (4.9%)	10 (8.2%)	13 (10.8)
Hematuria	0	4 (3.3%)	6 (5.0%)
Nasopharyngitis	10 (8.1%)	25 (20.5%)	18 (15.0%)
Headache	9 (7.3%)	14 (11.5%)	17 (14.2%)
Somnolence	0	1 (0.8%)	5 (4.2%)

At least 3% more frequent in placebo than lenabasum 20 mg twice daily groups

System Organ Class	Placebo N=123, n (%)	Lenabasum 5 mg BID N=122, n (%)	Lenabasum 20 mg BID N=120, n (%)
Anemia	7 (5.7%)	1 (0.8%)	2 (1.7%)
Arthralgia	20 (16.3)	15 (12.3%)	12 (10.0%)
Muscle weakness	4 (3.3%)	2 (1.6%)	0
Rotator cuff syndrome	4 (3.3%)	1 (0.8%)	0
Anxiety	5 (4.1%)	3 (2.5%)	1 (0.8%)
Productive cough	5 (4.1%)	0	0

Safety population of 365 subjects receiving at least 1 dose of study drug

Summary

Summary of RESOLVE-1 Phase 3 study results

- There were no significant differences between lenabasum 20 mg BID and placebo in the primary and secondary endpoints at Week 52
- Unprecedented improvement was observed in subjects in the placebo group. Improvement in the placebo group was greatest in subjects on background immunosuppressive therapies for ≤ 2 years treatment duration, especially mycophenolate
- Subjects treated with lenabasum 20 mg BID added to established immunosuppressive therapies had stable to little change in lung function assessed as FVC % predicted or FVC mL over 1 year, when compared to subjects treated with placebo
- Lenabasum was administered safely and was well-tolerated in this study, with no new safety signals or evidence of immunosuppression observed