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 14, 2016

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.)**

100 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))

Item 7.01. Regulation FD Disclosure.

On November 14, 2016, Corbus Pharmaceuticals Holdings, Inc. (the "Company") announced that it was hosting a conference call to provide an update on the Company's Phase 2 diffuse cutaneous systemic sclerosis ("systemic sclerosis") clinical program. A copy of the press release announcing the conference call is attached hereto as Exhibit 99.1. The Company is using the slides attached hereto as Exhibit 99.2 in connection with the conference call.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, 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, as amended (the "Exchange Act"), 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, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events

On November 14, 2016, the Company announced positive topline results from its Phase 2 study evaluating Resunab ("JBT-101") for the treatment of diffuse cutaneous systemic sclerosis ("systemic sclerosis"). JBT-101 out-performed placebo in the American College of Rheumatology (ACR) Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS) score, reaching 33% at week 16, versus 0% for placebo. The higher the CRISS score the greater the improvement; a CRISS score ³ 20% (CRISS20) can be considered a medically meaningful improvement. The difference in CRISS scores between JBT-101 and placebo groups over the trial period was significant (p = 0.044). Differences in categorical levels of CRISS responses and changes from baseline in the five individual domains of the CRISS score also supported clinical benefit of JBT-101.

The multi-center, double-blind, randomized, placebo-controlled Phase 2 study evaluated JBT-101's clinical benefit and safety in 27 subjects who received JBT-101 and 15 who received placebo. Subjects had disease duration up to 6 years and were allowed to receive stable doses of immunosuppressive drugs during this study. Subjects were randomized (2 to 1 overall JBT-101 to placebo ratio) to receive JBT-101 for the first four weeks at 5 mg once a day (n = 9), 20 mg once a day (n = 9), or 20 mg twice a day (n = 9) or placebo for the first four weeks, then all JBT-101 subjects received 20 mg twice a day for the next 8 weeks. All subjects were followed off study drug from weeks 13 through 16.

The primary efficacy objective was to evaluate clinical benefit in all subjects who received JBT-101 versus subjects who received placebo using the ACR CRISS score, a measure of improvement in systemic sclerosis. The CRISS is an exponentially weighted algorithm of change from baseline that includes the modified Rodnan skin score (mRSS), a measure of skin thickening, physician global assessment (MDGA), patient global assessment (PtGA), and Health Assessment Questionnaire - Disability Index (HAQ-DI), and forced vital capacity (FVC).

Results:

The median (25th percentile, 75th percentile) CRISS scores for the combined JBT-101 group and the placebo group at Weeks 4, 8, 12, and 16 are provided in the table below. The difference in CRISS scores between JBT-101 and placebo groups over the trial period was significant (p = 0.044), 1-sided mixed model repeated measures using rank transformed data.

	Median CRISS Score[1], % (25th percentile, 75th percentile)			
Group	**Week 4**	**Week 8**	**Week 12**	**Week 16**
JBT-101	3%	19%	27.5%	33%
n = 26	(0.6%, 11.4%)	(0.3%, 69.2%)	(1.9%, 67.8%)	(0.8%, 82.1%)
Placebo	1%	1%	1%	0%
n = 15	(0.3%, 8.8%)	(0.1%, 15.2%)	(0.1%, 60.1%)	(0.1%, 16%)

1) Modified intent to treat population, last observation carried forward

Results of secondary efficacy outcome measures supported the finding of clinical benefit of JBT-101, including numerical superiority of JBT-101 in each of the five domains of the CRISS score, with divergence starting early at Week 4 or Week 8.

There were no serious, severe, or unexpected adverse events related to JBT-101. One of 27 subjects (3.7% of subjects) who received JBT-101 withdrew from the study for an adverse event which was moderate dizziness.

The primary treatment period has been completed and subjects are now enrolled in a one- year open label extension to obtain data on long-term safety and durability of response. The Company received approval for an open-label extension to its Phase 2 clinical study of JBT-101 for systemic sclerosis from the U.S. Food and Drug Administration ("FDA") in April of 2016. The open-label extension enables all the participants in the study to receive JBT-101 for an additional 12 months.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 14, 2016 by Corbus Pharmaceuticals Holdings, Inc.
99.2	Presentation of Corbus Pharmaceuticals Holdings, Inc.

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 14, 2016

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated November 14, 2016 by Corbus Pharmaceuticals Holdings, Inc.
99.2	Presentation of Corbus Pharmaceuticals Holdings, Inc.

Exhibit 99.1

Corbus Pharmaceuticals Reports Positive Topline Results Showing Clear Signal of Clinical Benefit with Resunab (JBT-101) in Phase 2 Study in Systemic Sclerosis

– Difference in CRISS scores over trial period between JBT-101 and placebo groups was significant (p = 0.044) –
– Median CRISS score at week 16 reached 33% in JBT-101 group versus 0% in placebo group –
– Management to host conference call and webcast today at 8:30 a.m. EST –

Norwood, MA (November 14, 2016) – Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, today announced positive topline results from its Phase 2 study evaluating Resunab ("JBT-101") for the treatment of diffuse cutaneous systemic sclerosis ("systemic sclerosis"). JBT-101 out-performed placebo in the American College of Rheumatology (ACR) Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS) score, reaching 33% at week 16, versus 0% for placebo. The higher the CRISS score the greater the improvement; a CRISS score $\geq$ 20% (CRISS20) can be considered a medically meaningful improvement. The difference in CRISS scores between JBT-101 and placebo groups over the trial period was significant (p = 0.044). Differences in categorical levels of CRISS responses and changes from baseline in the five individual domains of the CRISS score also supported clinical benefit of JBT-101.

"This is the first double-blind, randomized, placebo controlled trial in diffuse cutaneous systemic sclerosis to demonstrate a clinical benefit using the CRISS as an endpoint, with a drug that was safe and well tolerated in the trial. These results bring hope to patients and their physicians that JBT-101 may be an effective drug for systemic sclerosis where currently there are no proven treatments," said Principal Investigator Robert Spiera, M.D., Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery, Weill Cornell Medical College in New York City.

Corbus management will host a conference call and live webcast, with accompanying presentation slides, for investors, analysts and other interested parties today at 8:30 a.m. ET (details below).

"The positive results of this study exceed our expectations and validate the unique mechanism of action of JBT-101. Our drug previously demonstrated clear and consistent evidence of activity in cellular and animal models as well as in healthy volunteers, repeatedly showing that its engagement with the CB2 receptor and its activation of inflammatory resolution translates into a potent effect on inflammation and fibrosis. With the data from this Phase 2 study, we now show that this mechanism of action provided clinical benefit in patients with systemic sclerosis in this trial," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company. "We look forward to the next stages in the clinical development of this drug. We are sincerely grateful to the patients, their physicians and the clinical staff who participated in this trial."

The multi-center, double-blind, randomized, placebo-controlled Phase 2 study evaluated JBT-101's clinical benefit and safety in 27 subjects who received JBT-101 and 15 who received placebo. Subjects had disease duration up to 6 years and were allowed to receive

stable doses of immunosuppressive drugs during this study. Subjects were randomized (2 to 1 overall JBT-101 to placebo ratio) to receive JBT-101 for the first four weeks at 5 mg once a day (n = 9), 20 mg once a day (n = 9), or 20 mg twice a day (n = 9) or placebo for the first four weeks, then all JBT-101 subjects received 20 mg twice a day for the next 8 weeks. All subjects were followed off study drug from weeks 13 through 16.

The primary efficacy objective was to evaluate clinical benefit in all subjects who received JBT-101 versus subjects who received placebo using the ACR CRISS score, a measure of improvement in systemic sclerosis. The CRISS is an exponentially weighted algorithm of change from baseline that includes the modified Rodnan skin score (mRSS), a measure of skin thickening, physician global assessment (MDGA), patient global assessment (PtGA), and Health Assessment Questionnaire - Disability Index (HAQ-DI), and forced vital capacity (FVC).

Results:

The median (25th percentile, 75th percentile) CRISS scores for the combined JBT-101 group and the placebo group at Weeks 4, 8, 12, and 16 are provided in the table below. The difference in CRISS scores between JBT-101 and placebo groups over the trial period was significant (p = 0.044), 1-sided mixed model repeated measures using rank transformed data.

	Median CRISS Score[1], % (25th percentile, 75th percentile)			
Group	**Week 4**	**Week 8**	**Week 12**	**Week 16**
JBT-101 n = 26	3% (0.6%, 11.4%)	19% (0.3%, 69.2%)	27.5% (1.9%, 67.8%)	33% (0.8%, 82.1%)
Placebo n = 15	1% (0.3%, 8.8%)	1% (0.1%, 15.2%)	1% (0.1%, 60.1%)	0% (0.1%, 16%)

1) Modified intent to treat population, last observation carried forward

Results of secondary efficacy outcome measures supported the finding of clinical benefit of JBT-101, including numerical superiority of JBT-101 in each of the five domains of the CRISS score, with divergence starting early at Week 4 or Week 8.

There were no serious, severe, or unexpected adverse events related to JBT-101. One of 27 subjects (3.7% of subjects) who received JBT-101 withdrew from the study for an adverse event which was moderate dizziness.

“We are excited about these positive clinical outcomes in the JBT-101 group in this study, especially given its short duration and relatively small number of diverse systemic sclerosis subjects,” stated Barbara White, M.D., Chief Medical Officer of the Company. “With these clinical data and findings of acceptable safety and tolerability, we plan to reach out to regulatory authorities to confirm the next steps forward.”

The primary treatment period has been completed and subjects are now enrolled in a one- year open label extension to obtain data on long-term safety and durability of response. Corbus received approval for an open-label extension to its Phase 2 clinical study of JBT-101 for systemic sclerosis from the U.S. Food and Drug Administration (“FDA”) in April of 2016. The open-label extension enables all the participants in the study to receive JBT-101 for an additional 12 months.

JBT-101 was granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis by the FDA in 2015.

For more information on the Phase 2 study with JBT-101 for the treatment of systemic sclerosis, please visit ClinicalTrials.gov and reference Identifier NCT02465437.

Conference Call and Webcast Information

Corbus management will host a conference call for investors, analysts and other interested parties today, November 14, 2016 at 8:30 am ET to discuss the topline data from the Phase 2 Study evaluating JBT-101 for the treatment of systemic sclerosis.

The conference call and live webcast will be accompanied by presentation slides. To participate in the call, please dial (877) 407-3978 (domestic) or (412) 902-0039 (international). The live webcast and accompanying slides will be accessible on the Events page of the Investors section of Corbus website, www.corbuspharma.com, and will be archived for 60 days.

About Systemic Sclerosis

Systemic sclerosis is a chronic, systemic autoimmune rheumatic disease with an unclear etiology. Systemic sclerosis affects approximately 90,000 people in the United States and Europe, with disease onset typically in mid-life. About 80 percent of systemic sclerosis patients are women. The disease process in systemic sclerosis includes activation of the immune system, with damage to small blood vessels and fibrosis of the skin on internal organs, including lungs, heart, kidneys, gastrointestinal tract and musculoskeletal system. Chronic disease burden, morbidity and mortality are significant. Cardiopulmonary disease is the major cause of death in systemic sclerosis. Immunosuppressive medications such as oral corticosteroids, methotrexate, cyclophosphamide, and mycophenolate mofetil are used to treat patients with more severe signs and symptoms of disease. Currently, there are no FDA-approved treatments specifically indicated for the treatment of systemic sclerosis, other than pulmonary artery hypertension secondary to connective tissue diseases such as systemic sclerosis.

About Resunab (“JBT-101”)

JBT-101 is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to the CB2 receptor expressed on activated immune cells and fibroblasts. CB2 activation triggers endogenous pathways that resolve inflammation and halt fibrosis. Preclinical and Phase 1 studies have shown JBT-101 to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. JBT-101 is designed to trigger the production of “Specialized Pro-resolving Lipid Mediators” that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. JBT-101 has direct effects on fibroblasts to halt tissue scarring. In effect, JBT-101 triggers endogenous pathways to turn “off” chronic inflammation and fibrotic processes, without causing immunosuppression.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Our lead product candidate, JBT-101, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and

fibrotic processes. JBT-101 is currently in Phase 2 clinical studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis, with a fourth Phase 2 trial in systemic lupus erythematosus planned to commence during the first half of 2017.

For more information, please visit www.CorbusPharma.com and connect with the Company on Twitter, LinkedIn, Google+ and Facebook.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

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Source: Corbus Pharmaceuticals Holdings, Inc.

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Exhibit 99.2

CORBUS PHARMACEUTICALS

JBT101-SSC-001 TOP-LINE DATA

PHASE 2 STUDY IN SYSTEMIC SCLEROSIS

NOVEMBER 14, 2016

NASDAQ:CRBP | CORBUSPHARMA.COM

FORWARD-LOOKING STATEMENTS

This presentation contains certain forward-looking statements, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. Additional written and oral forward-looking statements may be made by the Company from time to time in filings with the Securities and Exchange Commission (SEC) or otherwise. The Private Securities Litigation Reform Act of 1995 provides a safe-harbor for forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

AGENDA

- **Opening Remarks**
  - Yuval Cohen, Ph.D. – Chief Executive Officer
- **Review of JBT-101 Phase 2 Efficacy and Safety Top-Line Results**
  - Barbara White, M.D. – Chief Medical Officer
- **Comments**
  - Robert Spiera, M.D. – Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery, Weill Cornell Medical College in New York City
- **Q&A**
- **Closing Remarks**
  - Yuval Cohen, Ph.D. – Chief Executive Officer

TRIAL DESIGN

JBT101-SSc-001 PHASE 2 TRIAL DESIGN

- Double-blind, randomized, placebo-controlled, Phase 2 trial (Part A)
- 9 clinical sites in the U.S.
- Adults ages 18 to 70 with diffuse cutaneous systemic sclerosis (SSc)
- Inclusive eligibility criteria
  - Disease duration ≤ 3 years with any modified Rodnan skin score (mRSS), or
  - Disease duration > 3 and ≤ 6 years if mRSS ≥ 16, mRSS increased ≥ 5 points in the last 6 months, or elevated IL-6 or CRP
  - Immunosuppressive medications allowed
- ClinicalTrials.gov identifier NCT02465437

DURATION AND DOSING

- 16 week trial including 12 weeks of active dosing
- 2:1 overall ratio of JBT-101:placebo
- Weeks 1-4: JBT-101 5 mg once a day, JBT-101 20 mg once a day, JBT-101 20 mg twice daily or placebo in 2:2:2:3 randomization for dose response for biomarkers, plasma concentrations, safety, and early efficacy
- Weeks 5-12: JBT-101 20 mg twice daily and placebo to test efficacy and safety
- Weeks 13-16: Follow-up off drug
- Assessments
  - Safety: First dose and weeks 2, 4, 8, 12, and 16
  - Efficacy: Weeks 4, 8, 12, and 16

OBJECTIVES

Primary Objectives:

- Evaluate safety and tolerability
- Evaluate efficacy, using the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS) score

Secondary Objectives:

- Evaluate efficacy using levels of CRISS response and in each domain of the CRISS score
- Evaluate efficacy in other patient-reported outcomes
- Plasma concentrations of JBT-101
- Biomarkers of inflammation and fibrosis in blood and skin

First Study to Use CRISS Score as the Primary Efficacy Outcome

AMERICAN COLLEGE OF RHEUMATOLOGY CRISS SCORE

- Composite score of improvement from baseline
- Exponential, weighted algorithm
- CRISS score > 20% can be considered medically significant

Input

- 2 physician assessments – skin thickness (mRSS) and global health (MDGA)
- 2 patient assessments – Health Assessment Questionnaire Disability-Index (HAQ-DI) and global health (PtGA)
- Lung function – forced vital capacity (FVC)

Output

- Number between 0 – 1 or 0 – 100%
- Examples:
  - 5 point improvement in mRSS (medically meaningful) = 18% CRISS score
  - 0.22 improvement in HAQ-DI (medically meaningful) = 4% CRISS score
  - 5 point improvement in mRSS + 0.22 improvement in HAQ-DI = 32% CRISS score

SAFETY AND TOLERABILITY OUTCOMES

Safety Measures

- Treatment-emergent adverse events
- Other assessments: Vital signs, laboratory safety testing, electrocardiograms, Addition Research Center Inventory – Marijuana questionnaire

Tolerability Measures

- Discontinuation of study product because of treatment-emergent adverse events

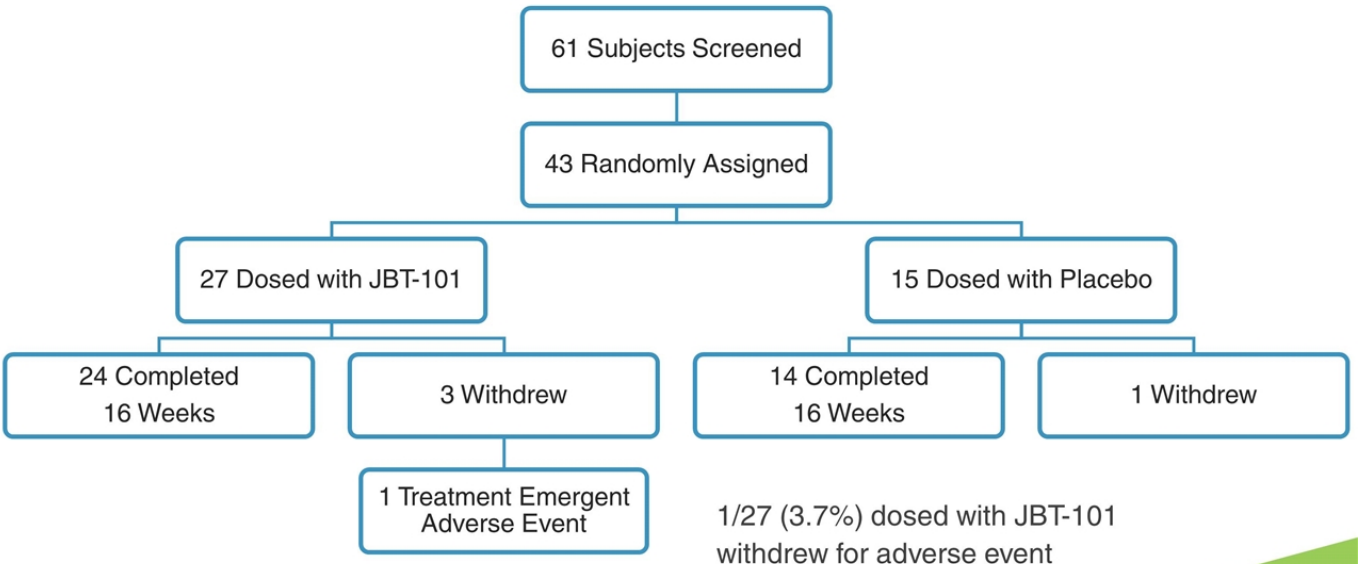
SAMPLE SIZE

Safety: 24 subjects in JBT-101 treatment group yield at least 95% probability of detecting adverse events that occur at a true rate of 12% or higher

- Not formally powered for efficacy
  - First-in systemic sclerosis Phase 2 study
  - First study to use CRISS as primary outcome

SUBJECT DISPOSITION AND BASELINE CHARACTERISTICS

SUBJECT DISPOSITION



1/27 (3.7%) dosed with JBT-101 withdrew for adverse event

DEMOGRAPHICS

Characteristics		JBT-101 n = 27	Placebo n = 15
Female, n (%)		23 (85.2%)	9 (60.0%)
Age, mean ± SD		48.7 ± 10.4	46 ± 11
Disease duration[1]	Months, mean ± SD	38 ± 19	41 ± 19
	> 3 ≤ 6 years	12 (42.1%)	7 (46.7%)
Immunosuppressive or immuno-modulating drugs		26 (92.9%)	12 (80.0%)

[1] Since first non-Raynaud's symptom

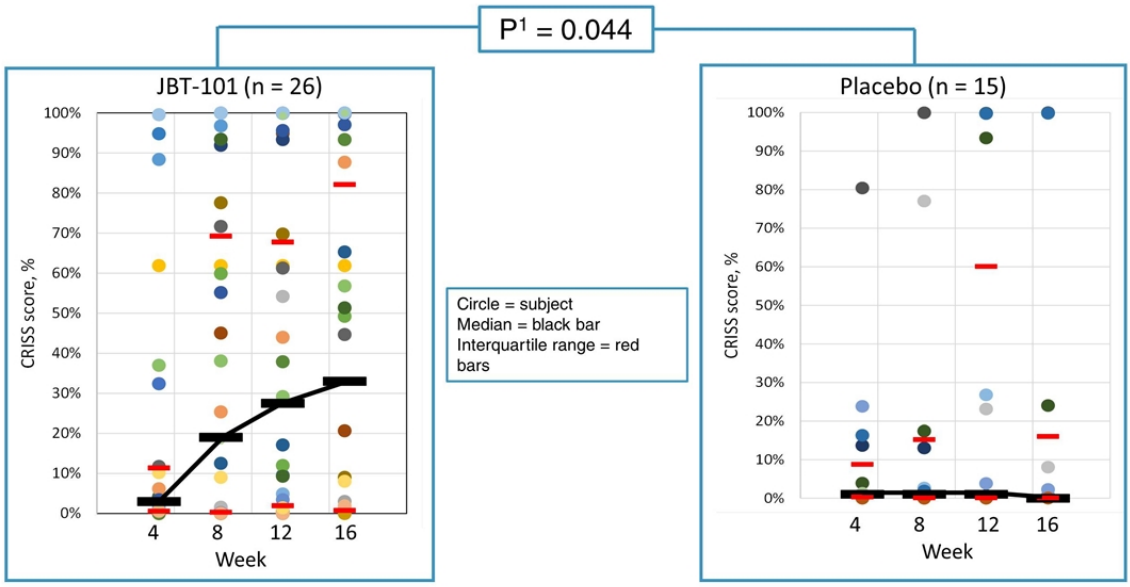
Inclusive Group of Subjects with Diffuse Cutaneous SSc

BASELINE CRISS DOMAINS

Domain	Mean ± SD (range)	
	JBT-101 n = 27	Placebo n = 15
Modified Rodnan skin score (0 – 51)	23.5 ± 10.4 (9 - 46)	26.2 ± 10.7 (8 - 47)
Physician global assessment (0-10)	4.6 ± 1.8 (2 - 10)	5.2 ± 2.1 (2 - 9)
Patient global assessment (0-10)	4.9 ± 2.3 (0 - 8)	4.9 ± 2.8 (0 - 9)
Health Assessment Questionnaire (0-3)	1.13 ± 0.80 (0 - 2.5)	1.51 ± 0.79 (0.1 - 2.6)
Forced vital capacity, % predicted	86.0 ± 13.4% (47.2 - 109.2%)	79.6 ± 10.3% (58.9 - 97.3%)

EFFICACY RESULTS

CRISS SCORES BY WEEK AND SUBJECT



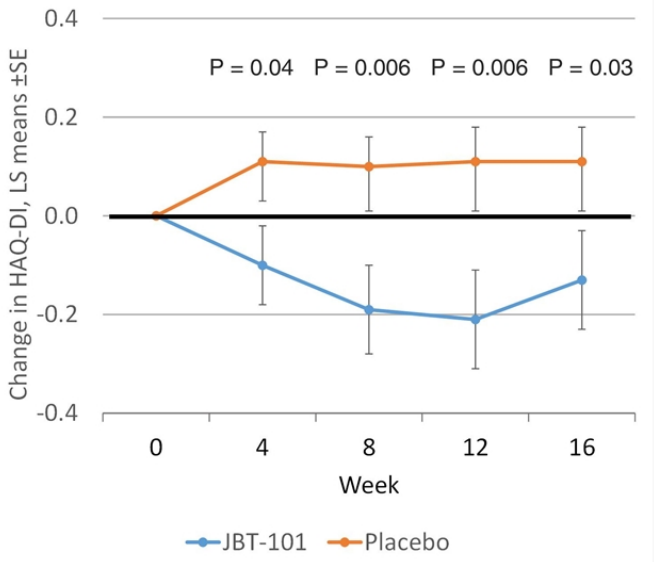
[1] mITT, LOCF population, 1- sided, mixed model repeated measures using rank transformed data

CRISS SCORES BY WEEK

Group	Median CRISS Score[1], % (Interquartile Range)[2]			
	Week 4	Week 8	Week 12	Week 16
JBT-101, n = 26	3.0% (0.6%, 11.4%)	19.0% (0.3%, 69.2%)	27.5% (1.9%, 67.8%)	33.0% (0.8%, 82.1%)
Placebo, n = 15	1.0% (0.3%, 8.8%)	1.0% (0.1%, 15.2%)	1.0% (0.1%, 60.1%)	0.0% (0.1%, 16.0%)

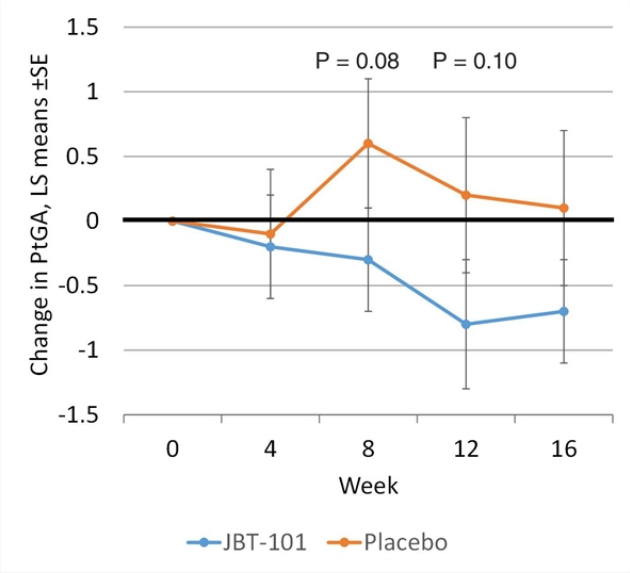
[1] Modified intent to treat population, last observation carried forward
[2] (25th percentile, 75th percentile)

CHANGE IN HEALTH ASSESSMENT QUESTIONNAIRE - DISABILITY INDEX (HAQ-DI) BY WEEK



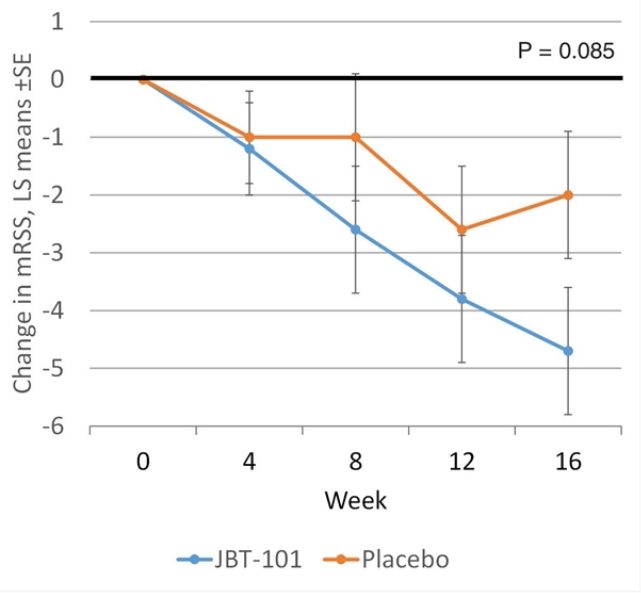
1-sided p value, least squares mean difference, analysis of covariance model

CHANGE IN PATIENT GLOBAL ASSESSMENT (PTGA) BY WEEK



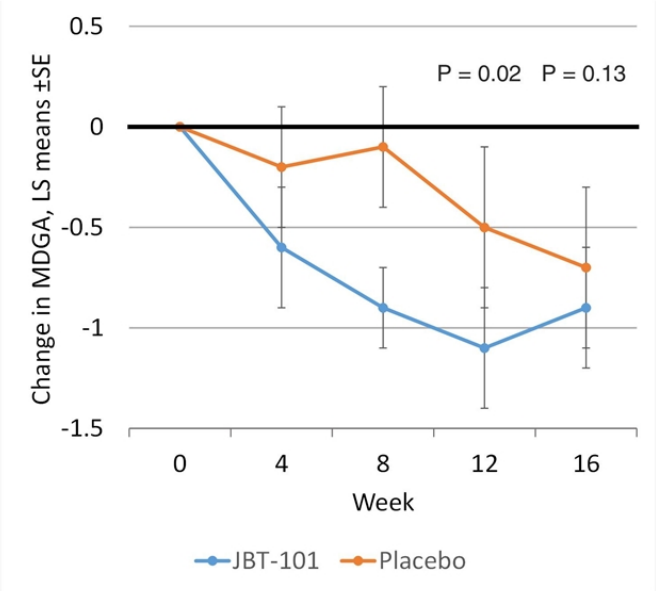
1-sided p value, least squares mean difference, analysis of covariance model

CHANGE IN MODIFIED RODNAN SKIN SCORE (MRSS) BY WEEK



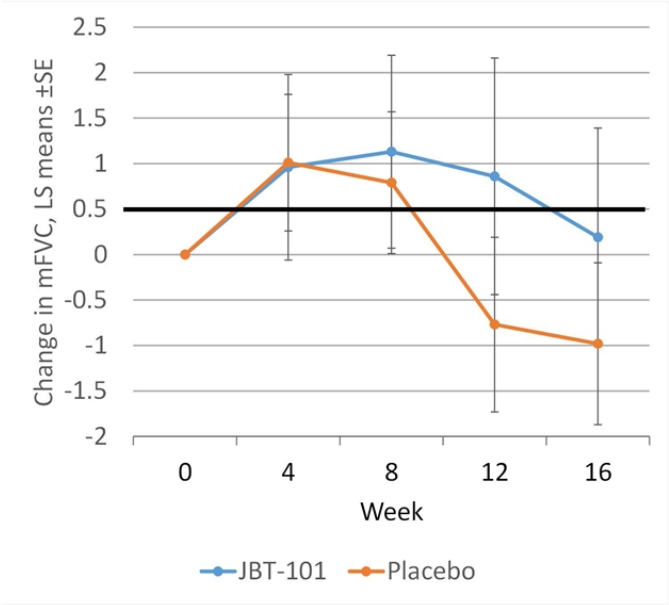
1-sided p value, least squares mean difference, analysis of covariance model

CHANGE IN PHYSICIAN GLOBAL ASSESSMENT (MDGA) BY WEEK



1-sided p value, least squares mean difference, analysis of covariance model

CHANGE IN FORCED VITAL CAPACITY (FVC) BY WEEK



1-sided p value, least squares mean difference, analysis of covariance model

SAFETY RESULTS

SAFETY: TREATMENT-EMERGENT ADVERSE EVENTS

- 2 serious TEAEs, both unrelated to study drug
  - JBT-101: dehydration of moderate severity treated in hospital
  - Placebo: abdominal pain and nausea of severe severity treated in hospital
- No unexpected TEAEs related to JBT-101
- Only two severe TEAEs occurred, both in a subject on placebo
- 70.4% versus 60.0% of JBT-101 versus placebo subjects experienced at least one TEAE
- 70 total TEAEs in the JBT-101 group versus 34 total TEAEs in the placebo group

TOLERABILITY

- JBT-101: 1 withdrawal at 4 weeks for TEAE of moderate dizziness probably related to study product

TEAES IN ≥ 2 SUBJECTS AND ≥ 5% MORE SUBJECTS IN ONE GROUP COMPARED TO THE OTHER GROUP

Organ System Class	Term	JBT-101 (n = 27)		Placebo (n = 15)	
		Subjects n (%)	Events n	Subjects n (%)	Events n
Gastrointestinal disorders	Nausea	1 (3.7%)	1	2 (13.3%)	3
	Diarrhea	2 (7.4%)	3		
General disorders	Fatigue	5 (18.5%)	5	1 (6.7%)	1
Infections	URI	4 (14.8%)	4		
Investigations	FVC decreased			2 (13.3%)	2
Nervous system disorders	Dizziness	6 (22.2%)	6	2 (13.3%)	3

CONCLUSIONS

- In a 16 week study in diffuse cutaneous SSc, JBT-101 provided significant and medially meaningful efficacy, as assessed with the ACR CRISS score
- Results of secondary efficacy outcome measures support efficacy of JBT-101 in diffuse cutaneous SSc
- The safety profile of JBT-101 was acceptable, with no serious, severe, or unexpected treatment-related adverse events associated with JBT-101 treatment
- JBT-101 was well tolerated
- The benefit: risk profile of JBT-101 in diffuse cutaneous SSc is favorable to date and supports discussions with regulatory authorities about next steps
- These data support cannabinoid receptor type 2 as a target for chronic inflammatory and fibrotic diseases

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COMMENTS

Q&A

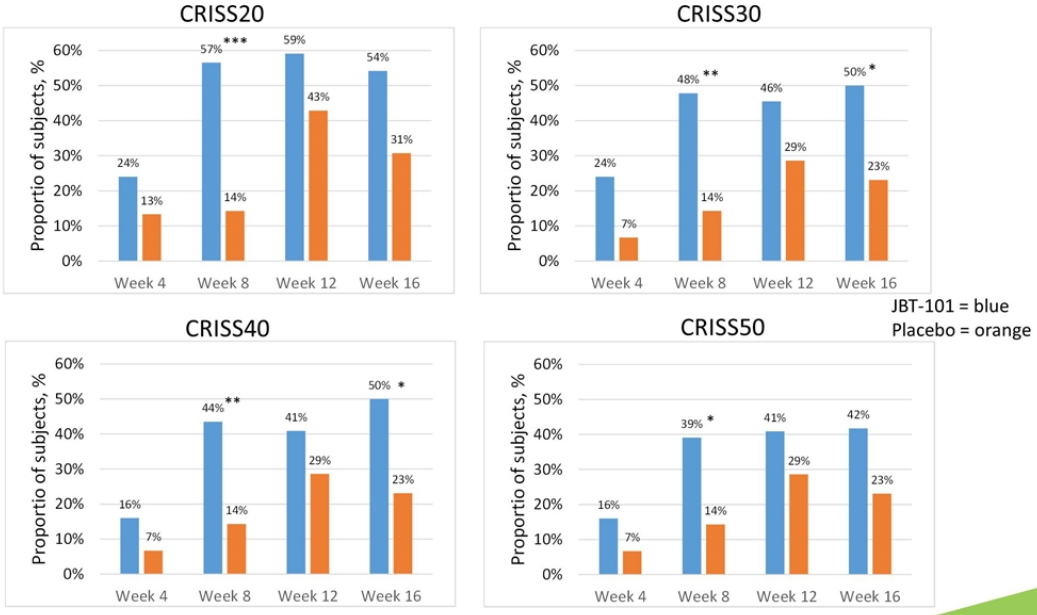
APPENDIX

EXAMPLES OF CATEGORICAL CRISS RESPONSES FROM THE TRIAL

- Number following CRISS indicates CRISS score is ≥ that number
- A decrease in all numbers except FVC is an improvement
- The individuals measurements that comprise the CRISS do not necessarily improve or worsen in parallel

Level	Change from Baseline					CRISS score
	mRSS	MDGA	PtGA	HAQ-DI	FVC	
not CRISS20	-5	0	0	0	0	18%
CRISS20	-5	-1	0	0	0	26%
CRISS30	-5	-1	-1	0	0	34%
CRISS40	-5	-1	-1	-0.125	0	44%
CRISS30	-5	-1	-1	-0.125	-2	34%
CRISS50	-5	-1	-1	-0.125	2	55%

CRISS CATEGORIES BY WEEK



JBT-101 = blue
Placebo = orange

* P ≤ 0.1, **P ≤ 0.05, ***P ≤ 0.01, mITT, observed values, one-tailed Fisher's exact test