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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 -- (Marketwired) -- 11/14/16 -- [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.

Group	Median CRISS Score ¹ , % (25 th percentile, 75 th percentile)			
	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.

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.

Investor Contact

Jenene Thomas

Jenene Thomas Communications, LLC

Phone: +1 (908) 938-1475

Email: jenene@jenenethomascommunications.com

Media Contact

David Schull

Russo Partners, LLC

Phone: +1 (858) 717-2310

Email: david.schull@russopartnersllc.com

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