

Corbus Pharmaceuticals Announces Completion of Phase 2 Study of Resunab for Systemic Sclerosis

Topline Data on Track to Be Reported in Q4 2016

NORWOOD, MA -- (Marketwired) -- 10/13/16 -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, announced today that it has completed the Phase 2 study evaluating Resunab for the treatment of diffuse cutaneous systemic sclerosis ("systemic sclerosis"). Corbus expects to report topline data from this study in the fourth quarter of 2016.

"We are grateful to all the individuals and clinicians who participated in this study and look forward to announcing top-line data as it becomes available this quarter," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company.

The multi-center, double-blind, randomized, placebo-controlled Phase 2 study was conducted at nine centers in the United States. This study evaluated Resunab's efficacy and safety in 42 individuals with systemic sclerosis over an 84-day treatment period and a 28-day follow-up period. The primary efficacy endpoint is the American College of Rheumatology Provisional Composite Response Index for diffuse cutaneous Systemic Sclerosis (CRISS) which predicts the probability (0-1 or 0-100% score) of improvement from baseline in randomized controlled trials in systemic sclerosis. The CRISS composite index is a weighted algorithm which includes change from baseline in five domains that are the modified Rodnan skin score, forced vital capacity % predicted, Health Assessment Questionnaire -- Disability Index, Patient Global Assessment and Physician Global Assessment. This Phase 2 study is also evaluating multiple secondary endpoints, including changes in the individual domains of the CRISS, other patient-reported outcomes, and biomarkers of inflammation and fibrosis in systemic sclerosis.

Resunab was granted <u>Orphan Drug Designation</u> and <u>Fast Track</u> status for the treatment of systemic sclerosis by the U.S. Food and Drug Administration ("FDA") in 2015. Corbus received <u>approval for an open-label extension to its Phase 2 clinical study of Resunab for systemic sclerosis</u> from the FDA in April of 2016. The open-label extension enables all the participants in the study to receive Resunab for an additional 12 months.

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

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

Resunab 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 Resunab to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Resunab is designed to trigger the production of "Specialized Proresolving Lipid Mediators" that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. Resunab has direct effects on fibroblasts to halt tissue scarring. In effect, Resunab 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, Resunab, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Resunab 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 <u>www.CorbusPharma.com</u> and connect with the Company on <u>Twitter</u>, <u>LinkedIn</u>, <u>Google+</u> and <u>Facebook</u>.

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 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: <u>david.schull@russopartnersllc.com</u>

Source: Corbus Pharmaceuticals Holdings, Inc.