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Corbus Pharmaceuticals Receives FDA Approval for Open-Label Extension to Its Phase 2 Trial of Resunab for Systemic Sclerosis

Company to Commence One-Year Open-Label Extension to Ongoing Study

NORWOOD, MA -- (Marketwired) -- 04/12/16 -- [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 the U.S. Food and Drug Administration ("FDA") has granted approval for a 12-month open-label extension study of the ongoing Phase 2 clinical trial of Resunab for the treatment of diffuse cutaneous [systemic sclerosis](#) ("scleroderma").

The goal of the open label extension study is to provide all subjects with the option of receiving Resunab following the completion of the 84-day treatment period in the ongoing double-blind placebo-controlled study and to collect long term safety and efficacy data on Resunab. All subjects in the 12-month extension study will receive Resunab, including those who received placebo in the current 84-day, double-blind placebo controlled trial. The same clinical endpoints used in the double-blinded placebo-controlled portion of the trial will be monitored throughout the 12-month extension study.

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, commented, "There is a clear unmet need for effective therapy options for individuals living with systemic sclerosis. Since the launch of the study, individuals have been very receptive to participating, and we look forward to furthering our understanding of the long-term safety and efficacy of Resunab through this open-label extension study."

"We are delighted to be able to offer the patients in our systemic sclerosis trial the opportunity to continue in a 12-month, open-label extension study of Resunab, upon their competition completion of the blinded portion of the trial," stated Barbara White, M.D., Chief Medical Officer of Corbus. "The additional 12 months of safety and efficacy data will be invaluable to the clinical advancement of this promising drug."

Yuval Cohen Ph.D., Chief Executive Officer of Corbus commented, "This is a noteworthy clinical milestone for Corbus, and we would like to express our gratitude to the subjects and

the clinical study teams participating in the study. We are grateful for the opportunity to further the clinical development of Resunab."

Resunab was granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of systemic sclerosis from the FDA in 2015. Corbus [launched its Phase 2 clinical trial](#) of Resunab for the treatment of systemic sclerosis in August of 2015. The multi-center, double-blind, randomized, placebo-control Phase 2 trial is being conducted in the United States and is designed to evaluate Resunab's safety and tolerability in up to 36 individuals with systemic sclerosis. In addition, the impact on clinical outcomes is measured using the Combined Response Index for diffuse cutaneous Systemic Sclerosis (CRISS) which includes both patient and physician-reported outcomes. Subjects in the study are treated for 84 days with a follow-up period of 28 days. The Phase 2 study also evaluates multiple secondary endpoints, including Resunab's mechanism of action and effect on biomarkers in systemic sclerosis. The Company expects to report top-line results from this study in the fourth quarter of 2016.

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 between 35,000-70,000 people in the United States, 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 and internal organs, including the 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, 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.

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 Pro-resolving Lipid Mediators" that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of pro-inflammatory eicosanoids and cytokines. 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, skin-predominant dermatomyositis and systemic lupus erythematosus.

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 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.

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