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Corbus Pharmaceuticals Commences Patient Enrollment in Phase 2 Clinical Study of Resunab(TM) for the Treatment of Systemic Sclerosis

Resunab Is a First-in-Class Drug That Induces Resolution of Inflammation; Study Will Treat Each Patient for 84 Days and Is Scheduled to Conclude in Q4 2016

NORWOOD, MA -- (Marketwired) -- 08/31/15 -- [Corbus Pharmaceuticals Holdings, Inc.](#) (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, and serious inflammatory and fibrotic diseases, announced today that patient enrollment has commenced in the Phase 2 clinical study of its investigational new drug [Resunab™](#) for the treatment of diffuse cutaneous [systemic sclerosis](#) ("systemic sclerosis").

Systemic sclerosis is a serious, life-threatening autoimmune disease that is characterized by chronic activation of the immune system, damage to blood vessels, and fibrosis (scarring) of the skin, lungs, and other internal organs. Systemic sclerosis affects predominately women in mid-life and is associated with significant morbidity and mortality. There are currently no FDA-approved drug therapies specifically for systemic sclerosis.

[Barbara White, M.D.](#), Chief Medical Officer of the Company, commented, "The launch of this study is an important milestone in the clinical development of Resunab. More importantly, Resunab has the potential to provide an entirely new approach to treat people with systemic sclerosis, who clearly need effective therapies without adversely suppressing their immune system."

Resunab is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to a receptor called CB2 on immune cells and fibroblasts. Numerous pre-clinical and human ex-vivo models have demonstrated that the binding of Resunab to CB2 triggers the production of "Specialized Pro-resolving Lipid Mediators" (SPMs) that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis. This resolution cascade restores chronically activated immune systems back to homeostasis and halts fibrosis, without causing immunosuppression.

The study is being led by 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. The study will be conducted in the United States at multiple clinics that specialize in the treatment of systemic sclerosis.

Dr. Spiera commented, "Resunab has anti-inflammatory and anti-fibrotic effects that are so relevant to the disease process in systemic sclerosis. We are hopeful that Resunab has the potential to address the significant unmet need for effective treatments that improve skin and lung involvement and other disease manifestations in people with this devastating disease. Currently there are limited treatments for these patients, and the mechanism of action of Resunab through induction of SPMs has the potential to provide clinical benefit to them."

The Phase 2 study is a double-blind, randomized, placebo-control trial that will enroll up to 36 individuals with systemic sclerosis who will be treated for 84 days with a follow up period of 28 days. The study is expected to take approximately 16 months to complete and is designed to evaluate Resunab's safety and tolerability, along with its potential impact on clinical outcomes as measured by the Combined Response Index for Systemic Sclerosis, or CRISS score. In addition, multiple secondary endpoints will evaluate Resunab's effect on patient-reported outcomes, as well as its mechanism of action and effect on biomarkers in this patient population. For more information on the Phase 2 study with Resunab for the treatment of systemic sclerosis, please visit [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02465437) and reference Identifier NCT02465437.

"We are pleased to have met all of the regulatory requirements (FDA, DEA, IRB) to begin enrolling patients in this clinical study. The launch of this trial represents the second clinical study now underway with Resunab, following [the launch of our Phase 2 dermatomyositis study last quarter](#) and we are on schedule for the imminent launch of our Phase 2 trial of Resunab for the treatment of [cystic fibrosis](#)," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company. "Once these three parallel Phase 2 trials are all launched, each in a distinct rare inflammatory disease, we will have implemented our initial clinical plans with Resunab and significantly increased the potential value of our lead product candidate. We look forward to data from these studies which we expect at the end of 2016."

The U.S. Food and Drug Administration granted [Orphan Drug Designation](#) to Resunab the treatment of systemic sclerosis in June of 2015 and recently designated [Fast Track status](#) to the Company's investigational drug development program in this indication.

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 drug that preferentially binds to the CB2 receptor expressed on activated immune cells. CB2 activation triggers endogenous

pathways that resolve inflammation and halt fibrosis. Pre-clinical and Phase 1 studies have shown Resunab to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in pre-clinical models of inflammation and fibrosis. Resunab triggers resolution of inflammation by increasing production of "Specialized Pro-resolving Lipid Mediators of Inflammation" and anti-inflammatory mediators, while reducing production of pro-inflammatory mediators and tissue inflammation. 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 drug that resolves chronic inflammation and fibrotic processes. Resunab is currently in Phase 2 studies for the treatment of diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis. A Phase 2 clinical trial with Resunab for the treatment of cystic fibrosis is scheduled to commence in 2015.

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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