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Corbus Pharmaceuticals Announces First Patient Dosed in Phase 2 Study of Resunab for Systemic Sclerosis

Corbus Expects to Report Top-Line Phase 2 Data in Systemic Sclerosis at End of 2016

NORWOOD, MA -- (Marketwired) -- 10/07/15 -- 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 the first subject was dosed in the Phase 2 clinical study of its investigational new drug Resunab™ for the treatment of diffuse cutaneous systemic sclerosis ("systemic sclerosis"). Resunab was granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis from the U.S. Food and Drug Administration earlier this year.

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, "Our patients recognize the unmet need for better therapies for systemic sclerosis, and are very receptive to participating in this careful early phase clinical trial aimed at evaluating the safety and potential efficacy of Resunab in treating this often devastating disease."

The multi-center, double-blind, randomized, placebo-control 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 will be measured using the Combined Response Index for diffuse cutaneous Systemic Sclerosis. Subjects in the study will be treated for 84 days with a follow-up period of 28 days. The Phase 2 study will also evaluate multiple secondary endpoints, including Resunab's effect on patient-reported outcomes, as well as Resunab's mechanism of action and effect on biomarkers in systemic sclerosis. For more information on the Phase 2 study with Resunab for the treatment of systemic sclerosis, please visit ClinicalTrials.gov and reference Identifier NCT02465437.

"People with systemic sclerosis face serious and sometimes life-threatening health issues. We believe Resunab offers these people the opportunity to improve the course of their disease in a way never tested before. As a CB2 agonist, Resunab has the potential to be a disease-modifying agent in systemic sclerosis, by resolving inflammation and stopping further fibrosis, without immunosuppression," commented Barbara White, M.D., Chief Medical Officer of the Company.

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. 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 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 that resolves chronic inflammation, bacterial infections, and fibrotic processes. Resunab is currently in Phase 2 studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis.

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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