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Corbus Pharmaceuticals' IND Receives Clearance From FDA to Initiate Phase 2 Trials in Scleroderma With Its Novel Specialized Pro-Resolving Mediator Drug Resunab™

Company to Initiate Phase 2 Clinical Study in Scleroderma Subjects in 2Q 2015; Company Anticipates Submitting Phase 2 Protocol for Cystic Fibrosis Under This IND in 2Q 2015

NORWOOD, MA -- (Marketwired) -- 03/09/15 -- [Corbus Pharmaceuticals Holdings, Inc.](#) (OTCQB: CRBP) (the Company), announced today that company's Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) is now open and it is authorized to initiate a Phase 2 clinical study with [Resunab™](#) for the treatment of [diffuse cutaneous systemic sclerosis](#) (scleroderma).

Scleroderma is a chronic, life-threatening inflammatory disease causing fibrosis of skin, joints and internal organs, affecting predominately women in mid-life. The diffuse form of the disease is associated with severe morbidity and high mortality. There are currently no approved therapies for scleroderma.

Corbus' Phase 2 clinical trial will be a double-blind, randomized, placebo-control study with multiple doses that will take place at several centers in the USA and enroll approximately 36 scleroderma patients that will each be treated daily for a period of three months with a follow-up period of one month. The study is expected to take 18 months to complete. This clinical study 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, the study will explore multiple secondary endpoints to better determine changes in the patients' inflammatory status.

Corbus plans to initiate this Phase 2 study in the second quarter of 2015. The company also intends to submit a Phase 2 protocol under this open IND for the treatment of [cystic fibrosis](#) in the second quarter of 2015.

"This IND clearance enables us to proceed with our Phase 2 study in scleroderma and represents a major step forward in our clinical development strategy for Resunab," stated [Barbara White, M.D.](#), Chief Medical Officer of Corbus Pharmaceuticals. "We look forward to

working with our clinical investigators to advance Resunab in this Phase 2 study aimed at establishing safety in this patient population and modifying the outcome of this disease. Based on its novel mechanism of activating the inflammatory resolution pathway, Resunab has the potential to become an important therapy for scleroderma patients as well as for potentially other diseases in which chronic inflammation and fibrosis are present."

"I am looking forward to investigating Resunab's potential to address such an important unmet medical need for the estimated 50,000 adults with scleroderma in the U.S. who could benefit from a potentially safe and effective treatment option for their severe, progressive and currently untreatable fibrosis," stated Lead Investigator, Robert Spiera, M.D., Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery in New York City.

"Moving forward, we look forward to the initiation of this clinical trial in scleroderma and submitting our Phase 2 clinical protocol to the FDA for the treatment of cystic fibrosis with Resunab," Dr. White concluded.

About Scleroderma

Systemic sclerosis (scleroderma) is a chronic connective tissue disease generally classified as one of the autoimmune rheumatic diseases with an unclear etiology. Scleroderma is found in two forms: limited and diffuse, with the diffuse cutaneous systemic form being most severe, affecting around 50,000 people in the United States. About 80% of those affected by scleroderma are women with an onset typically in her mid-life. In diffuse cutaneous systemic sclerosis, the body's immune system attacks and damages the skin causing it to thicken rapidly over a large area and may eventually involve the esophagus, gastrointestinal tract, lungs, kidneys, heart and other internal organs. It can also affect blood vessels, muscles and joints. There is currently no cure or effective therapy for scleroderma with pulmonary fibrosis being the most common cause of mortality. Inflammation is a driving force behind the disease symptoms, leading to progressive fibrosis and eventual mortality. In particular, the pro-inflammatory and pro-fibrotic cytokine TGF-beta has been identified as a key player in the progression of the disease and is considered an important target for therapy.

About Resunab[™]

Resunab[™] is a novel, oral specialized pro-resolving mediator drug with unique anti-inflammatory and anti-fibrotic activity. Pre-clinical and Phase 1 clinical studies have shown Resunab to have a favorable safety profile coupled with promising potency in pre-clinical models of inflammation and fibrosis. Resunab binds to the CB2 receptor on immune cells and triggers a process known as "inflammatory resolution," in effect turning chronic inflammation "off."

About Corbus Pharmaceuticals

Corbus Pharmaceuticals is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare life-threatening inflammatory-fibrotic diseases with clear unmet medical needs. Our lead product candidate

Resunab[™] is a novel oral specialized pro-resolving mediator anti-inflammatory drug scheduled to commence Phase 2 clinical trials for the treatment of Diffuse Cutaneous Systemic Sclerosis ("Scleroderma") and Cystic Fibrosis in 2015. For more information, please visit www.CorbusPharma.com.

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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