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Corbus Pharmaceuticals Receives FDA Clearance to Initiate Phase 2 Clinical Study of Resunab™ for the Treatment of Cystic Fibrosis

Phase 2 Clinical Study in Cystic Fibrosis Expected to Commence in 3Q 2015

NORWOOD, MA -- (Marketwired) -- 05/18/15 -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, life-threatening chronic inflammatory and fibrotic diseases, announced today that its Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") is now open and the Company is authorized to initiate a Phase 2 clinical study with Resunab™ for the treatment of cystic fibrosis ("CF"). Corbus expects to initiate a Phase 2 clinical study with Resunab in adults with CF within the next 90 days.

CF is a chronic, life-threatening, genetic disease that primarily affects the lungs and digestive system. CF is caused by a defective or missing CFTR protein resulting from mutations in the CFTR gene. In the lungs, the abnormal protein causes the buildup of thick, sticky mucus which, in turn, leads to recurrent bacterial infections, chronic inflammation and pulmonary fibrosis. Individuals with CF have an exaggerated, yet ineffective, innate immune response that compounds the inflammation and lung damage caused by the infections. The outcome is relentless, harmful inflammation leading to progressive lung damage and eventual failure impacting both the quality and duration of life.

Resunab is a novel synthetic oral drug that has the potential to treat the chronic pulmonary inflammation and fibrosis associated with disease progression in CF, regardless of an individual's specific CFTR gene mutation. Corbus recently received a $5 million development award from Cystic Fibrosis Foundation Therapeutics ("CFFT") to support the Company's Phase 2 clinical trial of Resunab for the treatment of CF.

"The CFFT, European Cystic Fibrosis Society, and key investigators provided expert and invaluable advice on the design of our Phase 2 CF study, and we are grateful to them for this assistance. With their help, we are pleased to have achieved this important regulatory milestone for our clinical development program," stated Barbara White, M.D., Chief Medical Officer of the Company. "The existing clinical safety data, as well as the pre-clinical efficacy data, points to the potential for Resunab to provide therapeutic benefit to CF patients. We believe that Resunab could potentially improve the clinical outcome for individuals with CF and favorably impact their lives."

"Based on its novel mechanism of action that turns on the resolution of the inflammation pathway, Resunab has the potential to treat the chronic lung inflammation and fibrosis at the root of the morbidity associated with CF," added James Chmiel, M.D., M.P.H., co-principal investigator of the Phase 2 study, specialist in pediatric pulmonary diseases in the Division of Pediatric Pulmonology, Allergy, Immunology and Sleep Medicine and Associate Director of the LeRoy W. Matthews Cystic Fibrosis Center at University Hospitals Rainbow Babies & Children's Hospital. "I believe Resunab has encouraging potential as a novel therapy for CF and look forward seeing its potentially life-changing outcome for individuals with CF."

The Phase 2 clinical trial is a multi-center, international, double-blind, randomized, placebo-control study with multiple doses and will enroll approximately 70 adults with CF. Study participants will each be treated daily for a period of 84 days, with a follow-up period of 28 days. The clinical trial is expected to be completed within 18 to 21 months. It is designed to evaluate Resunab's safety and tolerability, along with its potential impact on clinical outcomes as measured by FEV1, Lung Clearance Index and CFQ-R Respiratory Domain response. In addition, the study will explore multiple exploratory endpoints to determine the impact of Resunab on biomarkers for disease activity, inflammation and lung microbiota.

The Company plans to file for Clinical Trial Authorisations in multiple European countries to test Resunab in cystic fibrosis starting in the third quarter of 2015.

About Cystic Fibrosis

CF is a life-threatening, genetic disease that primarily affects the lungs and digestive system. It effects about 30,000 people in the United States (70,000 worldwide). People with CF inherit a defective CFTR gene that results in reduced chloride transport and a build-up of thick mucus in the lungs, pancreas and other organs. The patients have excessive and ineffective inflammatory responses in their lungs. The thick mucus traps bacteria in the airways resulting in infections and more inflammation. The chronic unresolved lung inflammation can lead to lung damage and scarring (fibrosis) and respiratory failure. Respiratory problems are the most serious and persistent complication for individuals with CF. For more information on cystic fibrosis, go to www.cff.org.

About Resunab™

Resunab™ is a novel synthetic oral drug with unique activity that has been shown to resolve inflammation and pro-fibrotic processes. Pre-clinical toxicology studies and previous 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 activated immune cells and triggers resolution of inflammation, reduction of pro-inflammatory pathways, and reduction in pro-fibrotic pathways, in effect turning chronic inflammation and fibrotic processes "off" without causing immunosuppression.

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 and fibrotic diseases. Our lead product candidate Resunab™ is a novel oral drug that resolves chronic inflammation and pro-fibrotic processes. Resunab is scheduled to commence Phase 2 clinical trials for the treatment of cystic fibrosis and diffuse cutaneous systemic sclerosis (scleroderma) 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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