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# Corbus Pharmaceuticals Commences Patient Enrollment in Phase 2 Clinical Study of Resunab(TM) for the Treatment of Cystic Fibrosis

## Study in Cystic Fibrosis Is the Third Phase 2 Clinical Trial Underway With Resunab for Treatment of Rare, Serious Inflammatory and Fibrotic Diseases

NORWOOD, MA -- (Marketwired) -- 09/21/15 -- [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 [cystic fibrosis](#) ("CF"). Resunab is a novel oral drug targeting the resolution of inflammation and fibrosis associated with disease progression in CF across all CFTR gene mutations. In a pre-clinical CF animal model, Resunab ameliorated inflammation, weight loss, bacterial infection and improved survival.

In April 2015, Corbus received a [\\$5 million development award from Cystic Fibrosis Foundation Therapeutics, Inc.](#) to support this multi-center, international Phase 2 study of Resunab in CF. The trial, which enrolls adult patients with CF, is being led in the U.S. by principal investigator [James Chmiel, M.D., M.P.H.](#), 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, and in the EU by co-principal investigator Professor J. Stuart Elborn, M.D., Dean, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, Northern Ireland.

The Phase 2 clinical trial with Resunab is a double-blind, randomized, placebo-control study with multiple doses that will enroll approximately 70 adults with CF irrespective of their CFTR mutation. Study participants will each be treated daily for a period of 84 days, with a follow-up period of 28 days. The study is expected to be completed within 18 to 21 months and is designed to evaluate Resunab's safety and tolerability, along with its potential impact on clinical outcomes as measured by FEV1, Lung Clearance Index, CFQ-R Respiratory Symptom scale, and lung microbiota. The trial will test the impact of Resunab on biomarkers of inflammation in the sputum and blood.

Dr. Chmiel commented, "Chronic inflammation is the root cause of the significant morbidity and mortality we see in the progression of CF. Resunab's novel mechanism of action

stimulates the body's natural machinery to resolve inflammation and halt tissue scarring. Because Resunab resolves inflammation independent of the underlying CF-related gene mutation or type of bacterial infection, it has the potential to improve the clinical outcome for a broad range of individuals with CF. We are excited that this trial is underway and eager to see the results once it is completed."

[Barbara White, M.D.](#), Chief Medical Officer of the Company, commented, "The start of the CF study is an important clinical development milestone for Resunab. We are hopeful that Resunab, as a novel treatment of inflammation and fibrosis, has the potential to be an effective treatment for all people with CF, to improve their health and help them better manage symptoms of their disease."

"Resunab is a first-in-class drug that induces the resolution of inflammation. The CF study is our third Phase 2 trial launched so far this year in a rare inflammatory disease, joining the Phase 2 trials in [systemic sclerosis](#) and [dermatomyositis](#) launched previously in 2015," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company. "The systemic sclerosis and CF studies are scheduled to conclude in the fourth quarter of 2016 and we look forward to reporting top-line data at that time."

For more information on the Phase 2 study with Resunab for the treatment of cystic fibrosis, please visit [ClinicalTrials.gov](http://ClinicalTrials.gov) and reference Identifier NCT02465450.

### ***About Cystic Fibrosis***

Cystic Fibrosis ("CF") is a chronic, life-threatening, genetic disease caused by inheriting two dysfunctional CFTR genes that normally regulate salt and water movement across cells in the respiratory and digestive systems. People with CF have thick, sticky mucus that clogs their airways, with recurrent bacterial infections and chronic inflammation in their lungs. In the gastrointestinal tract, they also have mucus accumulation, bacterial overgrowth, and inflammation. The dysfunctional CFTR genes cause an exaggerated inflammatory response that compounds the damage from a coexisting infection in the lungs and gut. CF results in destruction of lung tissue, lung fibrosis, pancreatic insufficiency, CF-related diabetes, malabsorption, malnutrition, growth retardation, and liver disease, including cirrhosis. The harmful inflammation and accompanying fibrosis in CF damages multiple organs, impairs organ function, reduces health-related quality of life, and can lead to death.

### ***About Resunab<sup>™</sup>***

Resunab<sup>™</sup> 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" (SPMs) 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<sup>™</sup>, 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](http://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.

### ***Investor Contact***

Jenene Thomas  
Jenene Thomas Communications, LLC  
Phone: +1 (908) 938-1475  
Email: [Email Contact](#)

### ***Media Contact***

David Schull or Marissa Goberdhan  
Russo Partners, LLC  
Phone: +1 (858) 717-2310  
Email: [Email Contact](#)  
Email: [Email Contact](#)

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