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## Corbus Pharmaceuticals Receives Orphan Designation for Resunab for the Treatment of Cystic Fibrosis in the European Union

**Company on track to complete Phase 2 study in cystic fibrosis in 2016; Phase 2 topline results expected Q1 2017**

NORWOOD, MA -- (Marketwired) -- 10/18/16 -- [Corbus Pharmaceuticals Holdings, Inc.](#) (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, announced today that the European Commission has granted Orphan Designation in the European Union for the Company's novel synthetic oral endocannabinoid-mimetic drug, [Resunab](#), for the treatment of [cystic fibrosis](#) ("CF").

The Company previously announced that Resunab was granted Orphan Drug Designation and Fast Track status [for the treatment of CF](#) and [the treatment of systemic sclerosis](#) in the U.S. by the Food and Drug Administration ("FDA"). Resunab is currently being evaluated in three Phase 2 trials in CF, [systemic sclerosis](#), and [dermatomyositis](#), respectively. A fourth National Institutes of Health-sponsored clinical study of Resunab in [systemic lupus erythematosus](#) is planned to begin in the first quarter of 2017.

"Receiving Orphan Designation for Resunab in the treatment of CF in the European Union is a noteworthy milestone in our global regulatory strategy for the clinical development of Resunab in CF," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company.

Corbus is currently testing Resunab in CF in the U.S. and Europe in a Phase 2, double-blinded, randomized, placebo-control trial that is supported in part by a [\\$5 million development award from the Cystic Fibrosis Foundation Therapeutics, Inc.](#) The study enrolled 89 adults who had CF and forced expiratory volume in 1 second (FEV1) percent predicted at least 40% predicted, without respect to their CFTR mutation, infecting pathogen, or baseline treatment. This Phase 2 trial will evaluate Resunab's safety, tolerability, and potential clinical benefit, as measured by FEV1 and Cystic Fibrosis Questionnaire-Revised Respiratory Symptom scale. The trial also will test the impact of Resunab on bacterial load in the lungs and biomarkers of inflammation in the sputum and blood. As previously reported, enrollment in the trial is complete, and the trial is on track to finish in 2016, with top-line safety and efficacy results anticipated early in 2017.

"There are no approved treatments for inflammation in CF, which is the major cause of lung damage in individuals with CF," added Barbara White, M.D., Chief Medical Officer of the

Company. "Resunab provided benefit in a murine model of lung inflammation in CF and in other pre-clinical models of lung inflammation and lung fibrosis. These data show Resunab's potential to improve lung inflammation and consequently potentially improve lung function and pulmonary exacerbations in people with CF. This Orphan Designation of Resunab for the treatment of CF was granted based on its potential to provide significant benefit to individuals with CF."

Orphan Designation is granted by the European Commission to drugs that are intended for the treatment, prevention or diagnosis of life-threatening or chronically debilitating rare diseases where no satisfactory method of diagnosis, prevention or treatment of the condition concerned is authorized. If such a method exists, then the medicine must be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of not more than five per 10,000 population in Europe. The Orphan Designation provides potential incentives from the European Union to develop a medicine for a rare disease, such as protocol assistance, reduced fees, funding from the European Commission for clinical trials, and protection from competition once the medicine is placed on the market, including 10 years of market exclusivity.

For more information on the Phase 2 study with Resunab for the treatment of CF, please visit [ClinicalTrials.gov](https://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. CF affects approximately 30,000 patients in the U.S and 75,000 patients worldwide. 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***

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. Preclinical and Phase 1 studies have shown Resunab to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Resunab is designed to trigger 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 multiple inflammatory mediators. 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 designed to resolve chronic inflammation, and fibrotic processes. Resunab is currently in Phase 2 clinical studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis, with a fourth Phase 2 trial in systemic lupus erythematosus planned to commence during the first half of 2017.

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.

Source: Corbus Pharmaceuticals Holdings, Inc.

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