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# Corbus Pharmaceuticals Announces FDA Orphan Drug Designation and Fast Track Status of Resunab(TM) for the Treatment of Cystic Fibrosis

## Second Orphan Drug Designation and Fast Track Status Granted to Resunab for Treatment of a Rare Inflammatory Disease

NORWOOD, MA -- (Marketwired) -- 10/20/15 -- [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 U.S. Food and Drug Administration ("FDA") has designated as a Fast Track development program and granted Orphan Drug Designation to the Company's investigational new drug [Resunab™](#) for the treatment of [cystic fibrosis](#) ("CF").

"These Orphan Drug and Fast Track Designations for Resunab in CF are another noteworthy milestone in our development and regulatory strategy and follow the [launch of our Phase 2 clinical study in CF](#) last month," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company. "Resunab has now received Orphan Drug and Fast Track Designation for the treatment of both systemic sclerosis and CF. We are pleased with the progression of our strategy focused on the treatment of significant unmet medical needs in rare inflammatory diseases."

The Company recently initiated an international, multi-center, Phase 2, double-blinded, randomized, placebo-control clinical study with multiple doses of Resunab in CF supported by a [\\$5 million development award from Cystic Fibrosis Foundation Therapeutics, Inc.](#) The study will enroll approximately 70 adults with CF, irrespective of their CFTR mutation.

"Resunab has demonstrated efficacy in pre-clinical models of inflammation and fibrosis, including a CF model, and to date, has a promising clinical safety profile in Phase 1 and 2 testing in humans," added Barbara White, M.D., Chief Medical Officer of the Company. "We believe Resunab has the potential to provide clinical benefit for individuals with CF and look forward to reporting top-line safety and efficacy results from our Phase 2 study in CF at the end of 2016."

The FDA Orphan Drug Designation program provides a special status to drugs and

biologics intended to treat, diagnose or prevent diseases and disorders that affect fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition, as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees.

A Fast Track designation enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

For more information on the Phase 2 study with Resunab for the treatment of cystic fibrosis, 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. 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. 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](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.

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