

# Corbus Pharmaceuticals Announces First Patient Dosed in Phase 2 Study of Resunab(TM) for Treatment of Cystic Fibrosis

## Phase 2 Top-Line Data in Cystic Fibrosis Expected to Be Reported at End of 2016

NORWOOD, MA -- (Marketwired) -- 10/15/15 -- 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 first subject was dosed in the Phase 2 clinical study of its investigational new drug Resunab To the treatment of cystic fibrosis ("CF").

"Patient dosing has commenced as planned in our CF trial and we are on track to report top-line Resunab safety and efficacy data in the CF patient population at the end of 2016," commented <u>Barbara White, M.D., Chief Medical Officer</u> of the Company. "Resunab's novel mechanism of action is not dependent on an individual's underlying CFTR gene mutation. As such, we believe Resunab has the potential for promising clinical benefits to all people with CF."

Resunab is a novel oral drug targeting the resolution of chronic inflammation and debilitating fibrosis associated with disease progression in CF across all CFTR gene mutations. In a preclinical CF animal model, Resunab ameliorated inflammation, weight loss, reduced bacterial infection and improved survival.

"Based on the pre-clinical and clinical safety and efficacy data reported to-date, I believe Resunab has the promise to improve outcomes for people with CF," added <u>James Chmiel, M.D., M.P.H.</u>, a principal investigator and 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. "Importantly, Resunab has the potential to target a significant unmet medical need in CF, without suppressing the body's natural immune response."

The international, multi-center, double-blind, randomized, multi-dose, placebo-control trial is designed to evaluate Resunab's safety and tolerability in up to 70 adults with CF irrespective of their CFTR mutation. Study subjects will be treated with Resunab daily for a period of 84 days, with a follow-up period of 28 days. The impact on clinical outcomes will be measured

by FEV1, Lung Clearance Index, CFQ-R Respiratory Symptom scale, and lung microbiota. Additionally, Resunab's impact on biomarkers of inflammation in the sputum and blood will be assessed. The Phase 2 trial in CF is expected to be completed by the end of 2016.

For more information on this study, please visit <u>ClinicalTrials.gov</u> 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 <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" 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 of 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 <u>www.CorbusPharma.com</u> and connect with the Company on <u>Twitter</u>, <u>LinkedIn</u>, <u>Google+</u> and <u>Facebook</u>.

#### 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

Source: Corbus Pharmaceuticals Holdings Inc