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Corbus Pharmaceuticals Completes Enrollment of Phase 2b Study of Lenabasum for Treatment of Cystic Fibrosis

- *Company expects to report topline data from study in the summer of 2020*
- *Primary endpoint of this study is reduction in pulmonary exacerbations*
- *Study enrolled participants regardless of CFTR mutation*
- *Stable background use of CFTR therapies was permitted*
- *Milestone advances Corbus' vision to pioneer the development of transformative medicines that target the endocannabinoid system*

Norwood, MA, Nov. 18, 2019 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical-stage drug development company pioneering transformative medicines that target the endocannabinoid system, today announced the completion of patient enrollment in the Phase 2b study evaluating the efficacy and safety of lenabasum for the treatment of cystic fibrosis (CF). The Company expects to report topline data from this study in the summer of 2020. Lenabasum has Orphan Drug Designation and Fast Track status for treatment of CF.

"We would like to take this opportunity to thank the participants in the study as well as the investigators and their staff," said Barbara White, M.D., Chief Medical Officer of Corbus. "Lenabasum represents a potential new anti-inflammatory treatment option for people with CF and recurring pulmonary exacerbations. Its potential benefit is without regard to CFTR mutation or the current treatment the patient is receiving. We look forward to announcing topline data from this study in the summer of 2020."

Corbus has enrolled 426 individuals with CF in the Phase 2b international, multicenter, randomized, double-blind, placebo-controlled study that is being conducted in North America, Europe, and Israel. Patients in the study are randomized 1:2:2 to either receive lenabasum 5 mg twice per day, lenabasum 20 mg twice per day or placebo twice per day for 28 weeks, with 4 weeks follow-up off active treatment.

The primary efficacy endpoint of the Phase 2b CF study is the event rate of pulmonary exacerbation. Secondary efficacy outcomes include other measures of pulmonary exacerbations, change in forced expiratory volume in 1 second (FEV1), % predicted, and change in Cystic Fibrosis Questionnaire-Revised respiratory domain score.

The Phase 2b CF study is funded in part by a Development Award for up to $25 Million from

the Cystic Fibrosis Foundation.

Lenabasum was granted Orphan Drug Designation for the treatment of CF by the FDA, Orphan Designation by the European Medicines Agency (EMA) and granted Fast Track status by the FDA. Lenabasum is not approved for the treatment of cystic fibrosis.

About Lenabasum

Lenabasum is a rationally designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2) and has been designed to resolve inflammation, limit fibrosis and support tissue repair. CB2 is preferentially expressed on activated immune cells and on fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to date, lenabasum has induced the production of pro-resolving lipid mediators that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Data from animal models and human clinical studies suggest that lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. Lenabasum has demonstrated promising activity in animal models of skin and lung inflammation and fibrosis in systemic sclerosis (SSc). Lenabasum is also active in animal models of lung infection and inflammation in cystic fibrosis and joint inflammation and scarring in rheumatoid arthritis.

Lenabasum has demonstrated acceptable safety and tolerability profiles in clinical studies to date. Lenabasum treatment was associated with improvement in multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and patients with dermatomyositis with active skin involvement but not currently active muscle involvement. Lenabasum treatment also was associated with a lower rate of and longer time to pulmonary exacerbations in a Phase 2 cystic fibrosis study. Additional clinical studies are being conducted to confirm these results and support applications for regulatory approval.

About Cystic Fibrosis

Cystic fibrosis (CF) is a chronic, rare, genetic disease caused by mutations of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. CF affects approximately 70,000 people in the U.S. and Europe.[1]

In people with CF, thick secretions build up in the lungs, pancreas and other organs. In the lungs, the mucus blocks airways, making it easy for bacteria to grow and infections to occur. These infections can severely damage the lungs over time and lead to respiratory failure.[2] People affected by CF may have trouble digesting their food and may develop diabetes as a complication due to the disease's effect on the pancreas.[3]

A person with CF may also experience pulmonary exacerbations (PEx), which are an acute worsening of inflammation in the lungs with an increase in respiratory symptoms (for example, cough, shortness of breath) accompanied by an acute decrease in lung function.[4] PEx are responsible for about half of long-term decline in lung function experienced by people with CF. More exacerbations are associated with greater lung function decline.[5] Nearly 1 in 3 people with CF require treatment for PEx in any given year, and treatment success of PEx is currently described as "suboptimal."[6,7] PEx can cost up to

$120K per year in people with severe lung disease and are associated with higher one-year risk of death.[8,9]

Despite the major advances in treatment of CF over the last several decades, there has been a minimal reduction in the proportion of individuals who have PEx treated with IV antibiotics.[6] Several classes of drugs have been considered to treat the underlying inflammation, though ibuprofen is the only anti-inflammatory drug currently recommended for the long-term treatment of CF airway inflammation. Despite this recommendation, very few eligible patients are prescribed ibuprofen because of side effects and monitoring requirements.[6,10]

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat inflammatory and fibrotic diseases by leveraging its pipeline of rationally designed, endocannabinoid system-targeting drug candidates. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist rationally designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis and systemic lupus erythematosus.

Corbus is also developing a pipeline of drug candidates targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to be peripherally restricted. Potential indications for CRB-4001 include nonalcoholic steatohepatitis (NASH), among others. Corbus expects data from a CRB-4001 Phase 1 safety study in 2020.

For more information, please visit www.CorbusPharma.com and connect with the Company on Twitter, LinkedIn, 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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