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Corbus Pharmaceuticals Reports Last Subject Visit in Phase 2b Study of Lenabasum for Treatment of Cystic Fibrosis

- *Topline data on schedule for Q3 2020*
- *Reduction in pulmonary exacerbations (PEx) as primary endpoint*
- *Study enrolled 426 participants regardless of CFTR mutation or background CFTR-targeting therapies*
- *Treatment of inflammation to reduce PEx remains a key unmet need in CF*
- *Study is funded in part by a Development Award for up to $25 Million from the Cystic Fibrosis Foundation*

Norwood, MA, June 22, 2020 (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 that the last subject completed their final visit in the Company's Phase 2b JBT101-CF-002 trial of lenabasum for the treatment of cystic fibrosis. Topline results from the study are on track to readout in the third quarter of 2020, following the topline data from the RESOLVE-1 Phase 3 systemic sclerosis study.

"Thank you to the clinical investigators and their staff, the people with CF in the study, and our team for their commitment and determination to complete the study on time even in the midst of a global pandemic," said Yuval Cohen, Ph.D, Chief Executive Officer. "We thank the Cystic Fibrosis Foundation for providing disease expertise and financial support to facilitate the design and execution of this study."

The Phase 2b trial is a multinational, 426-subject study evaluating the efficacy and safety of lenabasum in cystic fibrosis. This is a double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 5 mg twice per day, lenabasum 20 mg twice per day or placebo twice per day for 28 weeks, with 4 weeks safety follow-up off active treatment.

The primary efficacy endpoint is the event rate of pulmonary exacerbation (PEx). Secondary efficacy outcomes include other measures of PEx, 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 has been granted Orphan Drug designation and Fast Track designation for the treatment of cystic fibrosis by the U.S. Food and Drug Administration (FDA) and Orphan Designation for the treatment of cystic fibrosis from the European Medicines Agency (EMA).

About Lenabasum

Lenabasum is a rationally designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2), resolves inflammation, and limits fibrosis. 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.

Lenabasum is not approved for the treatment of systemic sclerosis, dermatomyositis, cystic fibrosis or systemic lupus erythematosus.

About Cystic Fibrosis

Cystic fibrosis (CF) is a chronic, rare, genetic disease affecting approximately 70,000 people worldwide. 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, limiting the ability to breathe over time.[1]

A person with CF may experience pulmonary exacerbations (PEx), which are an acute worsening of inflammation in the lungs with an increase in respiratory symptoms (e.g., cough, shortness of breath) accompanied by an acute decrease in lung function.[2] Despite advances in treatment of CF, patients still face high risk and treatment burden from PEx.

1 in 3 people with CF require treatment for PEx in any given year. On average, patients spend nearly 18 days hospitalized for PEx per year. [3] More exacerbations are associated with greater lung function decline.[4]

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 its Phase 1 safety study in 2020.

Lenabasum is not approved for the treatment of systemic sclerosis, dermatomyositis, cystic fibrosis or systemic lupus erythematosus. CRB-4001 is not approved for the treatment of NASH/NAFLD. For more information on Corbus' clinical programs, please visit here.

Please visit www.CorbusPharma.com and connect with the Company onTwitter, 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, including the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on our operations, clinical development plans and timelines, 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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