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## **Corbus Pharmaceuticals Announces Agreement with FDA on Phase 2b Cystic Fibrosis Study Design with Pulmonary Exacerbations as Sole Primary Endpoint**

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- *Multi-national Phase 2b is designed to provide clear evidence of clinical benefit of lenabasum (formerly known as anabasum) in patients with CF*
- *Study will enroll ~415 participants with CF 12 years of age and older regardless of underlying CFTR mutation, infection, or background medications*
- *First patient expected to be dosed this quarter*
- *Management to host conference call and webcast on Tuesday, January 30th at 10:30 a.m. EST*

Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, today announced that it has reached agreement with the U.S. Food and Drug Administration ("FDA") regarding the design of its next study of lenabasum (formerly known as anabasum), a novel, oral, pro-resolving drug, in the treatment of cystic fibrosis ("CF"). The Company and the FDA agreed that the event rate of pulmonary exacerbation is an acceptable sole primary efficacy endpoint for the clinical development program to support registration of lenabasum for the treatment of CF. Event rate of pulmonary exacerbation is the average number of pulmonary exacerbations per subject per time period. The FDA also agreed to the inclusion of adolescents 12-17 years of age alongside adults in the Phase 2b study. The Company expects the first patient to be dosed during this quarter.

The Phase 2b multicenter, double-blinded, randomized, placebo-controlled study will enroll approximately 415 subjects with CF who are at least 12 years of age and at increased risk for pulmonary exacerbations. Secondary efficacy outcomes include other measures of pulmonary exacerbations, change in Cystic Fibrosis Questionnaire-Revised Respiratory domain score and change in forced expiratory volume in 1 second (FEV1), % predicted. The study will be conducted in approximately 100 sites across North America, Europe, Israel and Australia. Subjects will be centrally randomized to one of three cohorts to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day for 28 weeks, with 4 weeks follow-up off active treatment. This Phase 2b CF study was designed with input from the Therapeutic Development Network of the Cystic Fibrosis Foundation and the European Cystic Fibrosis Society Clinical Trials Network.

"Pulmonary exacerbations are a key driver of morbidity and mortality in cystic fibrosis," said Barbara White, M.D., Chief Medical Officer of Corbus. "We now have agreement from the FDA that the event rate of pulmonary exacerbations is an acceptable primary efficacy outcome in the clinical development program to support registration of lenabasum for the treatment of CF. The FDA's input underscores the importance of new treatments that reduce the number of pulmonary exacerbations. With about 415 patients treated for 6-months, the next Phase 2 study is large enough and long enough to potentially provide statistically significant data regarding benefit of lenabasum in pulmonary exacerbations in CF."

Lenabasum is the only CF treatment currently in development designed to trigger the resolution of inflammation without immunosuppression. Its mechanism of action which reduces inflammation is applicable to all CF patients regardless of underlying CFTR mutation, infection, or background medications. Lenabasum reduced inflammatory cells and mediators in sputum and was associated with a favorable safety profile, reduced proportion of subjects with pulmonary exacerbations, and longer time to first pulmonary exacerbation in an earlier, completed 85-subject double-blinded, placebo-controlled 16-week Phase 2 study.

Yuval Cohen, Ph.D., Chief Executive Officer of Corbus, added, "The outcome of our meeting with the FDA represents a very significant milestone for our CF development program and builds on the foundation provided by the clinical data from our previous Phase 2 study. Lenabasum is the first pro-resolving drug to be tested for efficacy in CF and the first experimental therapeutic to be tested in CF patients with the event rate of pulmonary exacerbation as the sole primary efficacy endpoint, without a requirement from the FDA to consider FEV<sub>1</sub>% as a co-primary endpoint. We look forward to working closely with the stakeholders within the CF community on successfully executing this first of its kind trial."

Lenabasum was granted Orphan Drug Designation and Fast Track status for the treatment of CF by the FDA in 2015 and Orphan Drug Status from the European Medicines Agency (EMA) in 2016.

### ***Conference Call and Webcast Information***

Corbus management will host a conference call for investors, analysts and other interested parties on Tuesday, January 30, 2018 at 10:30 a.m. EST to discuss the Company's upcoming Phase 2 study evaluating lenabasum for the treatment of CF.

The conference call and live [webcast](#) will be accompanied by a slide presentation. To participate in the call, please dial (877) 407-3978 (domestic) or (412) 902-0039 (international). The live webcast and accompanying slides will be accessible on the [Events](#) page of the [Investors](#) section of Corbus website, [www.corbuspharma.com](http://www.corbuspharma.com), and will be archived for 60 days.

### ***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 chronic inflammation and recurrent bacterial infections in their lungs. In the gastrointestinal tract, they also have mucus accumulation, inflammation, and bacterial

overgrowth. Dysfunctional CFTR genes cause an exaggerated and ineffective inflammatory response that damages tissue and can be compounded by infection. 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 Pulmonary Exacerbations in Cystic Fibrosis***

A pulmonary exacerbation is acute worsening of the patient's day-to-day signs and symptoms of lung disease and is associated with worsening of inflammation at the start of the exacerbation. Failure to resolve lung inflammation during a given pulmonary exacerbation is associated with treatment failure, such as need to change antibiotics, prolonged antibiotic therapy, early recurrent of pulmonary exacerbation, and failure to recover lung function lost during the exacerbation. Pulmonary exacerbations in CF are associated with reduced survival, lung function, and patient quality of life and increased health-care burden. The annual average pulmonary exacerbation related costs in the United States can be as high as \$120,000 in patients with severe lung disease.

### ***About Lenabasum***

Lenabasum (formerly known as anabasum) is a synthetic, oral, small-molecule, selective cannabinoid receptor type 2 (CB2) agonist that preferentially binds to CB2 expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. CB2 activation also induces 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. Through activation of CB2, lenabasum also is designed to have a direct effect on fibroblasts to halt tissue scarring. Lenabasum is believed to induce resolution rather than immunosuppression by triggering biological pathways to turn "off" chronic inflammation and fibrotic processes. Lenabasum has demonstrated promising potency in preclinical models of inflammation and fibrosis. Preclinical and human clinical studies have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Further, the drug has demonstrated clinical benefit and positive impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis.

### ***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 rare, chronic, and serious inflammatory and fibrotic diseases. The Company's lead product candidate, lenabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis, and systemic lupus erythematosus.

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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