

# Corbus Pharmaceuticals Announces Phase 2b Study of Lenabasum for Treatment of Cystic Fibrosis Did Not Meet Primary Endpoint

- Study did not meet primary endpoint of reducing rate of pulmonary exacerbations
- Lenabasum treatment had a favorable safety profile and was well-tolerated
- Data to be presented at the upcoming North American Cystic Fibrosis Conference Oct.
   7-23

**Norwood, MA, Oct. 06, 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 topline results from its 28-week Phase 2b study of lenabasum in patients with cystic fibrosis (CF). The study enrolled patients in the U.S., Canada and Europe at high risk for recurrent pulmonary exacerbations (PEx). Subjects received lenabasum or placebo added to their background treatments for CF.

The CF-002 Phase 2b trial did not meet the primary endpoint of a statistically significant reduction in rate of new PEx per subject per 28 weeks. Lenabasum treatment had a favorable safety profile and was well-tolerated.

The topline data will be presented at the upcoming virtual North American Cystic Fibrosis Conference (NACFC), taking place October 7-23, 2020.

Barbara White, M.D., Chief Medical Officer and Head of Research of Corbus, said, "We are very disappointed that the study did not meet the primary endpoint. We look forward to providing more details of study results starting tomorrow at NACFC. We thank the participants, the staff at study sites, the Cystic Fibrosis Foundation, and the European Cystic Fibrosis Society Clinical Trials for their support and partnership throughout this study."

Yuval Cohen, Ph.D., Chief Executive Officer of Corbus, said, "We are immensely grateful to the Cystic Fibrosis Foundation for their invaluable support of this program from its inception. It has been a privilege to work with the CF community throughout this development program."

# Phase 2b CF-002 Trial Design

CF-002 was a multinational Phase 2b study evaluating the efficacy and safety of lenabasum

in CF. This was 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 was the event rate of new PEx per subject per 28 weeks, when the primary definition of new PEx was physician diagnosis of PEx, prescription of new antibiotics for that PEx starting more than 28 days after completion of the last antibiotic course for any previous PEx, with 4 out of 12 Fuch's criteria present in the subject. The Phase 2b CF study was funded in part by a Development Award for up to \$25 Million from the Cystic Fibrosis Foundation.

### About Lenabasum

Lenabasum is a novel, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2) and resolves inflammation and limits fibrosis in animal and human models of disease. CB2 is preferentially expressed on activated immune cells and on fibroblasts, muscle cells, and endothelial cells. Lenabasum has demonstrated acceptable safety and tolerability profiles in clinical studies to date.

### **About Corbus**

Corbus Pharmaceuticals Holdings, Inc. is a clinical-stage company focused on the development and commercialization of novel medicines designed to target the endocannabinoid system. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist that resolves chronic inflammation and limits fibrosis in animal and human models. Lenabasum is currently being evaluated in dermatomyositis and systemic lupus erythematosus. Corbus is also developing a pipeline of other drug candidates from its endocannabinoid system platform.

Lenabasum is not approved for the treatment of any indication. For more information on Corbus' clinical programs, please visit here.

For more information, visit <u>www.CorbusPharma.com</u>, and connect with us on <u>Twitter</u>, <u>LinkedIn</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 trial results, 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.

### **Corbus Pharmaceuticals Contacts:**

Ted Jenkins, Senior Director, Investor Relations and Corporate Communications

Phone: +1 (617) 415-7745 Email: <u>ir@corbuspharma.com</u>

Lindsey Smith, Director, Investor Relations and Corporate Communications

Phone: +1 (617) 415-7749

Email: <a href="mailto:mediainfo@corbuspharma.com">mediainfo@corbuspharma.com</a>

Christina Tartaglia Stern Investor Relations Phone: +1 (212) 362-1200

Email: christina.tartaglia@sternir.com



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