

# Corbus Announces Publication of Lenabasum Systemic Sclerosis Double-Blind, Placebo-Controlled Phase 2 Clinical Trial Results in Arthritis & Rheumatology

- These previously presented data demonstrated lenabasum improved efficacy outcomes and underlying disease pathology compared to placebo and had an acceptable safety profile in Phase 2 study
- Systemic sclerosis is a rare autoimmune disease affecting ~200,000 people in the U.S., EU and Japan, and has the highest mortality rate among the systemic autoimmune diseases
- Phase 3 study of lenabasum for the treatment of systemic sclerosis is on track for topline results in summer 2020

Norwood, MA, April 29, 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 (ECS), today announced the publication of results from the double-blind, randomized, placebo-controlled Phase 2 trial assessing the safety and efficacy of lenabasum in 42 patients with diffuse cutaneous systemic sclerosis in *Arthritis & Rheumatology*. The paper [doi:10.1002/art.41294] is titled "Safety and efficacy of lenabasum in a Phase 2 randomized, placebo-controlled trial in adults with systemic sclerosis." As previously reported, data showed treatment with lenabasum was associated with improvements across the primary endpoint, the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score and multiple secondary efficacy outcomes. The study results also demonstrated that lenabasum has an acceptable safety profile.

Efficacy and safety of lenabasum in systemic sclerosis are currently being evaluated in Corbus' global, 365-subject, RESOLVE-1 Phase 3 study. Baseline characteristics of subjects are similar to those in the Phase 2 study. RESOLVE-1 has enrolled 365 individuals with SSc in an international, multicenter, randomized, double-blind, placebo-controlled study. The primary efficacy endpoint is ACR CRISS score. The study is also evaluating multiple secondary endpoints, including changes in HAQ-DI, mRSS and FVC percent predicted.

Topline data from the RESOLVE-1 study remain on track for summer 2020.

### **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 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 <a href="here">here</a>.

Please visit <u>www.CorbusPharma.com</u> and connect with the Company 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 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, including 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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