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# Corbus Pharmaceuticals Completes Enrollment of RESOLVE-1 Phase 3 Study of Lenabasum for Treatment of Systemic Sclerosis

- *Company anticipates topline results of RESOLVE-1 study in the summer of 2020*
- *Systemic sclerosis (SSc) is a chronic, rare systemic autoimmune disease affecting approximately 200,000 people in the U.S., EU and Japan*
- *SSc has the highest mortality rate among the systemic autoimmune diseases; there are no FDA-approved treatments for this disease*
- *Milestone advances Corbus' vision to become the global leader in the treatment of inflammatory and fibrotic diseases by targeting the endocannabinoid system*

Norwood, MA, May 02, 2019 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company") today announced the completion of subject enrollment in RESOLVE-1, a Phase 3 study assessing the efficacy and safety of lenabasum for the treatment of systemic sclerosis (SSc). The Company expects to report topline results from this study in the summer of 2020. These data are anticipated to support an initial marketing application for lenabasum.

"We are grateful to the participants for their commitment and all our investigators and their staffs for their dedication and support of the study," said Barbara White, M.D., Chief Medical Officer of Corbus. "Completion of subject enrollment in this pivotal study is a key milestone to support the potential filing of a New Drug Application (NDA) in the U.S. and marketing authorization applications elsewhere."

RESOLVE-1 has enrolled 365 individuals with SSc in an international, multicenter, randomized, double-blind, placebo-controlled study that is being conducted in North America, Europe, Israel, Japan, South Korea, and Australia. Patients in the study are randomized 1:1:1 to either receive lenabasum 5 mg twice per day, lenabasum 20 mg twice per day, or placebo twice per day for 52 weeks with a follow-up period of 4 weeks.

The primary efficacy endpoint of RESOLVE-1 in the U.S. is the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score. The ACR CRISS score is calculated from weighted changes from baseline in five core outcome measures commonly used to evaluate treatment effect in trials for SSc: modified Rodnan Skin core (mRSS), Health Assessment Questionnaire - Disability Index (HAQ-DI), forced vital capacity (FVC) percent predicted, and patient and physician global

assessments of health related to SSc. The study is also evaluating multiple secondary endpoints in the U.S., including changes in HAQ-DI, mRSS and FVC percent predicted. Additionally, the Company is evaluating the safety and efficacy of lenabasum in an open-label extension of its Phase 3 study. The open-label extension enables all the participants in the study to continue to receive lenabasum following the conclusion of their trial period.

Lenabasum was granted Orphan Drug Designation for the treatment of SSc by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and was granted Fast Track status by the FDA.

**About Lenabasum**

Lenabasum is a rationally-designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2). CB2 is preferentially expressed on activated immune cells, fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to-date, lenabasum has induced the production of Specialized Pro-resolving lipid Mediators ("SPMs") that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Lenabasum is also believed to have a direct effect on fibroblasts to limit production of fibrogenic growth factors and extracellular connective tissue that lead to tissue fibrosis (scarring). 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 an 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 skin-predominant dermatomyositis. ACR CRISS score was the primary efficacy endpoint in the Phase 2 study of lenabasum in diffuse cutaneous SSc and showed a greater treatment effect in subjects who received lenabasum compared to placebo in that study. 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 and/or planned to confirm these results and support applications for regulatory approval.

**About Systemic Sclerosis**

Systemic sclerosis (SSc), a form of scleroderma, is a chronic, rare systemic autoimmune disease affecting approximately 200,000 people in the U.S., EU and Japan.[1] SSc is more common in adults and women than in men and children, and typically occurs in people aged 30 to 50 years old.[2] The disease is characterized by chronic inflammation, fibrosis (for example, scarring) and small blood vessel damage in multiple organs in the body.[3] Scleroderma is an autoimmune disease, but it is unknown why the body's immune system is activated and stays active, damaging the body's own tissue.[4] SSc has the highest mortality rate among the systemic autoimmune diseases.[5] There is no cure for systemic sclerosis, and there are no FDA-approved treatments for this disease.[6]

**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 endocannabinoid system-targeting synthetic drug candidates. The Company's lead product candidate, lenabasum, is a novel, synthetic, oral, selective cannabinoid receptor type 2 (CB2) agonist 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 from more than 600 novel compounds targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist. Potential indications for CRB-4001 include NASH, among others. Corbus plans to start a Phase 1 study of CRB-4001 in 2019, intended to be followed by a National Institutes of Health (NIH)-funded proof-of-concept Phase 2 study.

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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