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Corbus Pharmaceuticals Reports Last Subject Visit in RESOLVE-1 Phase 3 Study of Lenabasum for Treatment of Systemic Sclerosis

- *Topline data on schedule for summer 2020*
- *Systemic sclerosis (SSc) is a rare, serious and life-threatening autoimmune disease affecting ~200,000 people in the U.S., EU and Japan*
- *There are no FDA-approved therapies for the overall treatment of SSc*

Norwood, MA, May 27, 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 RESOLVE-1 Phase 3 trial of lenabasum for the treatment of systemic sclerosis. Topline results from the study are on track for summer 2020.

"We would like to express our sincere gratitude to our staff, our clinical collaborators and the study participants for their commitment and dedication leading to the study completing on time even in the midst of a global pandemic," said Yuval Cohen, Ph.D, Chief Executive Officer.

The RESOLVE-1 Phase 3 trial is a multinational study evaluating the efficacy and safety of lenabasum in systemic sclerosis. This was a double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 20 mg twice per day, or lenabasum at 5 mg twice per day, or placebo twice per day for 52 weeks, with a 28-day safety follow-up. Study subjects may then elect to participate in the ongoing open-label extension of RESOLVE-1.

The primary efficacy endpoint is a composite score known as the ACR CRISS, measured at Week 52. ACR-CRISS was also the primary endpoint in the preceding Phase 2 study recently published in *Arthritis & Rheumatology*.

Secondary efficacy endpoints include change from baseline at Week 52 in modified Rodnan skin score, Health Assessment Questionnaire- Disability index, and forced vital capacity (FVC) percent predicted. Three hundred and sixty-five patients were enrolled in the study.

Baseline disease characteristics of subjects in RESOLVE-1 are similar to those in the Phase 2 study and were recently presented at American College of Rheumatology (ACR) 2019 Annual Meeting and European League Against Rheumatism (EULAR) 2020 E-Congress.

Lenabasum has been granted Orphan Drug designation and Fast Track designation for the treatment of systemic sclerosis from the U.S. Food and Drug Administration (FDA) and Orphan Designation for the treatment of systemic sclerosis 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 Systemic Sclerosis

Systemic sclerosis (SSc), a form of scleroderma, is a chronic, rare, debilitating autoimmune disease affecting approximately 200,000 people in the North America, EU and Japan.[1] Although systemic sclerosis is rare, it is considered one of the most life-threatening rheumatic diseases.[2] Systemic sclerosis affects the skin and internal organs and is driven by inflammation and fibrosis (scarring of tissue) leading to severe damage and failure of multiple organs including the skin, joints, tendons, gastrointestinal tract, lungs, heart, blood vessels and kidneys.[3] There is no cure for systemic sclerosis, and current treatments address the clinical manifestations of the disease, not the underlying mechanisms that drive inflammation and fibrosis.[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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Source: Corbus Pharmaceuticals Holdings, Inc.