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Corbus Pharmaceuticals Completes Enrollment in DETERMINE Phase 3 Study of Lenabasum for Treatment of Dermatomyositis

- *12-month, double-blind, placebo-controlled, multi-national study enrolled 176 participants*
- *Topline results expected in fourth quarter of 2021*
- *Dermatomyositis is a rare, systemic autoimmune disease with characteristic skin and muscle involvement, serious morbidity, and increased mortality*

Norwood, MA, Aug. 05, 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 the completion of subject enrollment in **DETERMINE**, a Phase 3 study assessing the efficacy and safety of lenabasum for the treatment of dermatomyositis ("DM"). The Company expects to report topline results from this study in the fourth quarter of 2021.

"We are grateful to the participants for their commitment and to all of our investigators and their staff for their support of the study and dedication to completing enrollment on time, despite COVID-19," said Barbara White, M.D., Chief Medical Officer and Head of Research of Corbus. "Enrollment exceeded our expectations, which we think speaks to the unmet need of dermatomyositis patients for new treatment options, especially options without some of the toxicities associated with chronic immunosuppression."

The Company's Phase 3 **DETERMINE** study has enrolled 176 subjects in the largest, randomized, double-blind, placebo-controlled DM study to date. This study is being conducted in North America, Europe, and Asia. Patients in the study are randomized 2:1:2 to either receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day or placebo twice per day for 52 weeks with a follow-up period of 4 weeks.

The primary endpoint of **DETERMINE** is efficacy of lenabasum compared to placebo as measured by the American College of Rheumatology ("ACR")/ European League Against Rheumatism 2016 Total Improvement Score ("TIS") in myositis at 52 weeks, a weighted composite measure of improvement from baseline in six core set items that include physician directed assessments of Physician Global Activity, Manual Muscle Testing-8, and Extramuscular Global Activity, patient-reported outcomes of Patient Global Activity and Health Assessment Questionnaire, and biomarkers of muscle enzymes.[‡] Multiple secondary

outcomes including Cutaneous Dermatomyositis Activity and Severity Index activity score are being evaluated. Additionally, the Company is evaluating the safety and efficacy of lenabasum in an open-label extension of the **DETERMINE** Phase 3 study. The open-label extension enables participants who complete the double-blind study period to continue to receive lenabasum.

Lenabasum was granted Orphan Drug Designation for the treatment of dermatomyositis from the U.S. Food and Drug Administration (FDA) and 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 Dermatomyositis

Dermatomyositis (DM), a form of myositis, is a chronic, rare, inflammatory, clinically heterogeneous, life-threatening autoimmune disease affecting approximately 80,000 people in North America, EU and Japan.¹ The signs and symptoms of DM reflect multi-organ involvement, which includes distinctive skin rashes usually accompanied by proximal muscle weakness, and can also include pulmonary, cardiac, gastrointestinal, and joint involvement.² Patients with DM can have recurrent disease flares or chronic progressive disease activity, with increased mortality.^{3,4} The current mainstay of treatments include FDA-approved systemic glucocorticoids, adrenocorticotropic hormone analogue and off-label use of glucocorticoid-sparing immunosuppressive agents.^{5,6} There is significant unmet need for new treatments to achieve disease control in DM because of limited efficacy or toxicity of immunosuppressive agents or refractory disease.^{7,8}

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 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, 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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‡Aggarwal R, et al. "2016 American College of Rheumatology/European League Against Rheumatism criteria for minimal, moderate, and major clinical response in adult dermatomyositis and polymyositis: An International Myositis Assessment and Clinical Studies Group/Paediatric Rheumatology International Trials Organisation Collaborative Initiative." *Ann Rheum Dis*. 2017 May ; 76(5): 792–801

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Source: Corbus Pharmaceuticals Holdings, Inc.