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Corbus Pharmaceuticals Initiates "DETERMINE" Phase 3 Study in Dermatomyositis

- *DM is a rare systemic autoimmune disease that affects ~80,000 individuals in the U.S., EU and Japan and has a 5-year mortality rate as high as 30%*
- *This marks Company's second Phase 3 program in rare autoimmune diseases*
- *Lenabasum has Orphan Drug Designation for treatment of DM in U.S. and EU, and unencumbered commercial rights across all geographies*
- *Design of 12-month multi-national study in 150 adults with dermatomyositis developed with guidance from U.S., EU, and Japanese regulatory authorities*

Norwood, MA, Dec. 17, 2018 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company with the industry's leading pipeline focused on treating inflammatory and fibrotic diseases through the endocannabinoid system ("ECS") pathways, announced today the start of the Company's Phase 3 trial, titled "**D**ETER**M**INE," designed to evaluate the efficacy and safety of its investigational drug lenabasum for the treatment of dermatomyositis ("DM"). The Phase 3 study design is consistent with guidance from the U.S. Food and Drug Administration ("FDA") at an end-of-Phase 2 meeting, formal consultation with Japanese regulatory authorities ("PMDA"), and scientific advice from European regulatory authorities. Dermatomyositis is a rare and serious multisystem inflammatory autoimmune disease that characteristically affects muscle and skin and can also involve the lungs, heart, joints, and gastrointestinal tract. The disease is characterized by significant morbidity, disability, and mortality despite the current standard-of-care treatment with corticosteroids or other immunosuppressive medications.

"We are delighted to have achieved many important regulatory and clinical milestones in the development of lenabasum this year, now including the initiation of this Phase 3 DM study," said Barbara White, M.D., Chief Medical Officer of Corbus. "The double-blinded placebo-controlled 1-year study is designed to include subjects with active muscle and/or skin disease who represent the clinical spectrum of DM, making results applicable to the broad DM population. If the efficacy data from this single Phase 3 study are positive and the safety profile continues to be favorable, we intend to approach regulatory authorities about a registration package for lenabasum for treatment of DM."

The **D**ETER**M**INE Phase 3 study will test efficacy and safety of lenabasum in approximately 150 adults with DM. Subjects will be randomized to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day in a 2:1:2 ratio. The primary

efficacy outcome at Week 52 will be Total Improvement Score (TIS), which is a weighted composite measure of improvement from baseline in six endpoints, including Physician Global Assessment of Disease Activity, Physician Global Assessment of Extramuscular Disease Activity, Patient Global Assessment of Disease Activity, Health Assessment Questionnaire (patient-reported disability), Manual Muscle Testing, and muscle enzymes. Evaluation of key organ involvement – muscle, skin, and lungs, will be included in secondary efficacy outcomes. Change from Baseline in the Cutaneous Dermatomyositis Activity and Severity index ("CDASI") activity score will be a secondary efficacy outcome.

"The start of **D**ETER**M**INE represents an important milestone for Corbus and a major step forward towards our vision of becoming a leader in treating inflammatory and fibrotic diseases by targeting the endocannabinoid system with what we believe is one of the industry's most innovative pipelines. This study is our third late-stage study in orphan chronic inflammatory diseases, that combined, address approximately 150,000 patients in the U.S. alone," commented Yuval Cohen, Ph.D., CEO of Corbus.

Progression to Phase 3 testing is supported by data from a Phase 2 trial of lenabasum in subjects with refractory skin-predominant DM. The safety and tolerability profile of lenabasum in DM patients has been acceptable to date, with no serious or severe AEs related to lenabasum. All subjects who started the Phase 2 study completed the double-blind, placebo-controlled 16-week part of the study, and all subjects who started dosing in the open-label extension of the Phase 2 study completed 1-year of dosing. Lenabasum treatment was associated with an improvement of minus 9.4 points from baseline in the CDASI activity score, a validated outcome measure of skin disease severity, at the end of the 16-week double-blinded placebo-controlled portion of the study. At 12 months in the open-label extension, continued improvement in inflammatory skin involvement was observed in DM subjects using a composite outcome, the CDASI activity score. The CDASI activity score improved from study start by a mean of -17.6 points at 12 months in the OLE. An improvement of -4 to -5 points in CDASI activity score is considered medically important, and 84% of subjects had improvement in CDASI activity score exceeding -10 points at 12 months in the OLE. Lenabasum treatment was associated with consistent improvement in other measures of skin disease activity, physician global assessment, patient global assessment, and patient-reported function and symptoms during the double-blinded placebo-controlled portion of the study. Multiple key efficacy outcomes further improved in the ongoing open-label extension Phase 2 trial.

Lenabasum has been granted Orphan Drug Designation for the treatment of DM and Orphan Designation for the treatment of DM from the EMA.

About Dermatomyositis

Dermatomyositis (DM), a form of idiopathic inflammatory myositis, is a chronic, rare systemic autoimmune disease affecting approximately 80,000 people in the US, EU and Japan. The disease is typically diagnosed in adults between 50 and 60 years old, although it can occur in children, and females are more commonly affected than males. Dermatomyositis is characterized by chronic inflammation, scarring or loss of cells in multiple organs, and damage to blood vessels. As with SSc, it is unknown why the body's immune system becomes and stays activated, damaging the skin, muscles, and other organs in people with DM.

People with DM have inflammatory skin rashes with or without muscle weakness and involvement of multiple other organs. The symptoms of DM vary depending on the organs involved and the severity of the involvement. Typically, reddish or purple inflammatory skin rashes appear on the face, chest, and hands. The rashes can be painful, intensely itchy, light-sensitive, and the skin can even ulcerate. The skin rashes generally precede, accompany, or follow progressive muscle weakness, although DM can occur without clinically apparent muscle involvement. Some people with DM need devices to help with arising or walking because of muscle weakness. Deposits of calcium in the skin and muscles can be painful or ulcerate. Other symptoms of DM can include: tiredness and weight loss from systemic inflammation; shortness of breath and limitation of daily activities from cardiopulmonary involvement; pain from joint and tendon inflammation; heartburn and trouble swallowing food from involvement of the esophagus; and pain in the hands because of Raynaud's

phenomenon from small blood vessel involvement. Malignancy is more common in DM. Overall mortality rate in DM estimated to be about 30% at 5 years.

Immunosuppressive or immunomodulating drugs are typically prescribed to control DM disease activity overall or in major organs. Drugs that are used include high dose prednisone, methotrexate, mycophenolate, cyclophosphamide, azathioprine, rituximab, intravenous immunoglobulin, and anti-malarial drugs. These treatments may be associated with significant side effects, such as serious infections, or may not be well-tolerated. FDA-approved treatments for DM include systemic corticosteroids and adrenocorticotropic hormone analogue.

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 favorable safety and tolerability profiles in clinical studies to date. Lenabasum improved multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and skin-predominant dermatomyositis. Lenabasum also reduced 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 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 licensed the exclusive worldwide rights to develop, manufacture and market drug candidates from more than 600 novel compounds targeting the endocannabinoid system from Jenrin Discovery LLC. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to eliminate blood-brain barrier penetration and subsequent brain CB1 receptor occupancy that mediates the neuropsychiatric adverse events associated with first-generation CB1 inverse agonists. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction and acute interstitial nephritis, among others. Corbus plans to enter 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.

Investor Contacts:

Institutional Investor Inquiries
Ted Jenkins, Senior Director, Investor Relations and Communications
Corbus Pharmaceuticals, Inc.
Phone: +1 (617) 415-7745
Email: ir@corbuspharma.com

All Other Investor Inquiries
Jenene Thomas
Jenene Thomas Communications, LLC
Phone: +1 (833) 475-8247
Email: crbp@jtcir.com

Media Contact

Lindsey Smith
Phone: +1 (617) 415-7749
Email: mediainfo@corbuspharma.com

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