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Corbus Pharmaceuticals to Commence Phase 3 Study of Lenabasum for the Treatment of Rare Autoimmune Disease Dermatomyositis

- *Phase 3 study follows positive 16-weeks Phase 2 data and further improvement in efficacy outcomes with open-label extension dosing at six months*
- *12-month 150 subject study with ACR/EULAR 2016 Total Improvement Score in myositis as primary efficacy outcome*
- *Approximately 80,000 dermatomyositis patients in the U.S. with few treatment options and 5-year mortality rates as high as 30%*

Norwood, MA, July 25, 2018 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, announced today that the Company will proceed with a Phase 3 trial evaluating the efficacy and safety of lenabasum for the treatment of dermatomyositis ("DM"). Dermatomyositis is a rare and serious multisystem inflammatory autoimmune disease affecting muscle and skin. The U.S. Food and Drug Administration ("FDA") provided guidance on the overall study design of this trial at a recent end-of-Phase 2 meeting. The Phase 3 study is planned to begin at the end of 2018.

The international Phase 3 trial will be a 1-year, double-blind, randomized, placebo-controlled study testing 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 will be American College of Rheumatology ("ACR")/ European League Against Rheumatism 2016 Total Improvement Score ("TIS") in myositis, a composite measure of improvement from baseline in six endpoints: Physician Global Activity, Patient Global Activity, Health Assessment Questionnaire, Manual Muscle Testing, and measurement of muscle enzymes and extra muscular activity. Change in the Cutaneous Dermatomyositis Activity and Severity index ("CDASI") activity score will be a secondary efficacy outcome.

"Current treatment options for DM patients are largely restricted to immunosuppressive drugs, including high-dose corticosteroids as first-line treatment," said [Barbara White, Chief Medical Officer](#) of Corbus. "DM is a rare disease, the unmet medical need for new treatments is great, and lenabasum treatment was associated with improvement in multiple efficacy outcomes in the Phase 2 study. Our goal is to approach the FDA about registration

of lenabasum for treatment of DM should the data from this single Phase 3 study be positive. Dermatomyositis and systemic sclerosis, another rare and serious autoimmune disease in which lenabasum is currently in Phase 3 testing, share many clinical manifestations and aspects of disease pathophysiology. Our confidence in moving into Phase 3 testing in DM is anchored in consistent and often medically meaningful improvements in multiple physician- and patient-reported outcomes in Phase 2 testing in both diseases.”

“Our vision at Corbus is to become a leader in rare inflammatory fibrotic diseases, and we believe this upcoming Phase 3 dermatomyositis study brings us a step closer to that goal. The DM study will be our third late-stage study across three rare indications, that combined address approximately 150,000 patients in the U.S.,” 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. 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. Improvement of minus 5 points or more in CDASI activity score is considered medically meaningful. Improvement in CDASI activity score increased further to minus 15.4 points at the end of 28 weeks open-label dosing, with more than 80% of subjects achieving ≥ 10 -point improvement from the start of the Phase 2 study and approximately 50% achieving low skin disease activity. 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.

The Company recently received FDA Orphan Drug Designation for lenabasum for the treatment of DM. The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent diseases and disorders that affect fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition, as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees.

About Dermatomyositis

Dermatomyositis is a rare and serious systemic autoimmune condition characterized by skin and muscle involvement. Like other autoimmune diseases, it affects more women than men and morbidity is more severe in non-white populations. Muscle inflammation (myositis) is a common characteristic of the disease and can manifest as weakness. Distinctive skin lesions also characterize the disease, with red sometimes raised lesions, ulcerations or erosions, calcium deposits, photosensitivity, itch, and hair loss as well as other abnormalities. Dermatomyositis affects as many as 80,000 people in the US, EU, and Japan. Mortality is high with reported 5-year survival of 70% and 10-year survival of 57%. Standard of care includes antimalarial drugs and potent immunosuppressive agents, which can lead to significant adverse effects.

About Lenabasum

Lenabasum is a synthetic, oral, small-molecule, selective cannabinoid receptor type 2 (CB2)

agonist that preferentially binds to CB2 expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. CB2 activation also induces the production of specialized pro-resolving lipid mediators that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. Through activation of CB2, lenabasum also is designed to have a direct effect on fibroblasts to halt tissue scarring. Lenabasum is believed to induce resolution rather than immunosuppression by triggering biological pathways to turn "off"

chronic inflammation and fibrotic processes. Lenabasum has demonstrated promising potency in preclinical models of inflammation and fibrosis. Preclinical and human clinical studies have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Further, the drug has demonstrated clinical benefit and positive impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis.

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 rare, chronic, and serious inflammatory and fibrotic diseases. The Company's lead product candidate, lenabasum, is a novel, synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis, and systemic lupus erythematosus.

For more information, please visit www.CorbusPharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Google+](#) 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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