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Corbus Pharmaceuticals to Commence Single Phase 3 Study of Anabasum for Treatment of Systemic Sclerosis Following Guidance Received from Successful End-of-Phase 2 Meeting with FDA

NORWOOD, MA -- (Marketwired) -- 04/05/17 -- [Corbus Pharmaceuticals Holdings, Inc.](#) (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, today announced that the Company will be proceeding with a single Phase 3 study to support a New Drug Application ("NDA") for anabasum for the treatment of diffuse cutaneous [systemic sclerosis](#) ("systemic sclerosis"). The U.S. Food and Drug Administration ("FDA") has provided guidance on the development program and the design of the study. The international Phase 3 trial will be a double-blind, randomized, placebo-controlled study conducted in approximately 270 adults with systemic sclerosis. Subjects will be randomized to receive anabasum 20 mg twice per day, anabasum 5 mg twice per day, or placebo twice per day. Corbus expects to enroll its first patient in this study in the fourth quarter of 2017.

"With the conclusion of a successful end-of-Phase 2 meeting with FDA, we believe we have a clear path forward to advance the clinical development of anabasum to support an NDA for the treatment of systemic sclerosis," said [Barbara White, M.D., Chief Medical Officer](#) of Corbus. "We are engaging the European Medicines Agency ("EMA") in similar discussions. We look forward to potentially providing systemic sclerosis patients with an effective therapeutic option for a disease for which there remains significant unmet medical need."

The primary efficacy outcome of the Phase 3 study will be change from baseline at week 52 in modified Rodnan skin score ("mRSS"), a measure of skin thickening and a validated clinical outcome in systemic sclerosis. In the [positive Phase 2 study reported in November 2016](#), the mean improvement from baseline in mRSS for anabasum-treated subjects was greater than placebo-treated subjects and considered medically meaningful. The improvement in mRSS was accompanied by statistically significant improvement in patient-reported skin symptoms and reduced expression of genes associated with inflammation and fibrosis in skin biopsies from trial subjects. Secondary outcomes of the Phase 3 study will include the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis ("ACR CRISS") score, a novel composite measure of clinical improvement from baseline that incorporates change from baseline in mRSS, lung function, and other physician and patient reported outcomes. Anabasum-treated subjects in the

Phase 2 study showed significant improvement in ACR CRISS score versus placebo-treated subjects.

"We are delighted with the design of this single Phase 3 study in systemic sclerosis," said [Yuval Cohen, Ph.D., CEO](#) of Corbus. "Successful execution of this trial is a top priority for Corbus. We believe we have the team and the capital to make this happen."

Anabasum was granted [Orphan Drug Designation](#) and [Fast Track](#) status by the FDA for the treatment of systemic sclerosis in 2015 and [Orphan Drug Designation](#) by the EMA in January 2017. Corbus also has an ongoing [12-month, open-label extension to its Phase 2 clinical study of anabasum for systemic sclerosis](#).

About Systemic Sclerosis

Systemic sclerosis is a chronic, systemic autoimmune rheumatic disease with an unclear etiology. Systemic sclerosis affects approximately 90,000 people in the United States and Europe, with disease onset typically in mid-life. About 80 percent of systemic sclerosis patients are women. The disease process in systemic sclerosis includes activation of the immune system, with damage to small blood vessels and fibrosis of the skin on internal organs, including lungs, heart, kidneys, gastrointestinal tract and musculoskeletal system. Chronic disease burden, morbidity and mortality are significant. Cardiopulmonary disease is the major cause of death in systemic sclerosis. Immunosuppressive medications such as oral corticosteroids, methotrexate, cyclophosphamide, and mycophenolate mofetil are used to treat patients with more severe signs and symptoms of disease. Currently, there are no FDA-approved treatments specifically indicated for the treatment of systemic sclerosis, other than pulmonary artery hypertension secondary to connective tissue diseases such as systemic sclerosis.

About Anabasum

Anabasum is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to the CB2 receptor expressed on activated immune cells and fibroblasts. CB2 activation triggers endogenous pathways that resolve inflammation and halt fibrosis. Preclinical and Phase 1 studies have shown anabasum to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Anabasum is designed to trigger 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. Anabasum has direct effects on fibroblasts to halt tissue scarring. In effect, anabasum triggers endogenous pathways to turn "off" chronic inflammation and fibrotic processes, without causing immunosuppression.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Our lead product candidate, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Anabasum is currently in Phase 2 clinical studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis, with a fourth Phase 2 study in systemic lupus erythematosus planned to commence during the first half of 2017.

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 studies, 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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