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Corbus Pharmaceuticals Receives Orphan Designation for JBT-101 for the Treatment of Systemic Sclerosis in the European Union

NORWOOD, MA -- (Marketwired) -- 01/17/17 -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, announced today that the European Commission has granted Orphan Designation in the European Union ("EU") for the Company's novel synthetic oral endocannabinoid-mimetic drug, JBT-101 ("Resunab") for the treatment of systemic sclerosis.

"We are pleased to receive our second Orphan Designation in the EU for JBT-101. We look forward to the continued advancement of our global clinical and regulatory development strategy for JBT-101 for the treatment of serious and rare inflammatory and fibrotic diseases," stated Yuval Cohen, Ph.D., Chief Executive Officer.

The Company previously announced that JBT-101 was granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis and cystic fibrosis ("CF") by the U.S. Food and Drug Administration ("FDA") and Orphan Designation for the treatment of CF in the EU.

Corbus reported positive topline data from its Phase 2 study of JBT-101 for the treatment of systemic sclerosis in November 2016. The results of the Phase 2 study showed that JBT-101 improved the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (CRISS) score, reaching a median of 33% at week 16 in the JBT-101 treated group versus 1% for placebo. Changes from baseline in the five individual domains of the CRISS score also supported clinical benefit of JBT-101.

Orphan Designation is granted by the European Commission to drugs that are intended for the treatment, prevention or diagnosis of life-threatening or chronically debilitating rare diseases where no satisfactory method of diagnosis, prevention or treatment of the condition concerned is authorized. If such a method exists, then the medicine must be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of not more than five per 10,000 population in Europe. The Orphan Designation provides potential incentives for the sponsor from the EU to develop a medicine for a rare disease, such as protocol assistance, reduced fees, funding from the European Commission for clinical trials, and protection from competition once the medicine is placed on the market, including ten years of market exclusivity.

For more information on the Phase 2 study with JBT-101 for the treatment of systemic sclerosis, please visit ClinicalTrials.gov and reference Identifier NCT02465437.

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 JBT-101

JBT-101 is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to the cannabinoid receptor type 2 (CB2) 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 JBT-101 to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. JBT-101 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. JBT-101 has direct effects on fibroblasts to halt tissue scarring. In effect, JBT-101 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. The Company's lead product candidate, JBT-101, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. In November 2016, Corbus reported positive topline data results from a Phase 2 study in diffuse cutaneous systemic sclerosis, showing clear signal of clinical benefit with JBT-101. The Company recently completed a Phase 2 study of JBT-101 for the treatment of cystic fibrosis with topline data expected to be announced before the end of the first quarter of 2017. Additionally, JBT-101 is being evaluated in a Phase 2, 12-month open label extension study in systemic sclerosis, a Phase 2 study in skin-predominant dermatomyositis, with a 12-month open label extension study in dermatomyositis and another Phase 2 study in systemic lupus erythematosus planned to commence in the first quarter 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 trials, 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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