Corbus Pharmaceuticals Presented Data from Phase 2 Study of Anabasum for the Treatment of Systemic Sclerosis at the EULAR 2017 Annual Meeting

NORWOOD, MA -- (Marketwired) -- 06/15/17 -- 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 safety and efficacy data from its previously completed Phase 2 clinical study of anabasum (formerly known as JBT-101) for the treatment of diffuse cutaneous systemic sclerosis was presented earlier today at the European League Against Rheumatism (“EULAR”) Annual Meeting in Madrid, Spain. The presentation included a review of the Phase 2 topline data previously announced, additional data from the study regarding Patient-Reported Outcomes Measurement Information System (PROMIS)-29, and additional analysis of the previously-reported CRISS domains and transcriptome data.

The abstract titled, “A Phase 2 study safety and efficacy of anabasum (JBT-101) in systemic sclerosis” was presented by Robert Spiera, M.D., Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery, Weill Cornell Medical College in New York City, and Principle Investigator of Corbus’ Phase 2 systemic sclerosis clinical study. To view the presentation, please click here.

Anabasum was granted Orphan Drug Designation and Fast Track status for the treatment of systemic sclerosis from the FDA in 2015 and Orphan Designation from 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 and expects to report data from this study in the fourth quarter of 2017.

Following an end-of-Phase 2 meeting with the FDA, Corbus announced its plans to commence a Phase 3 study of anabasum for the treatment of systemic sclerosis in the fourth quarter of 2017. 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 complete enrollment of this 52-week study in 2018 and expects to conclude the study by the end of 2019.

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 human clinical 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 also is designed to have 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 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, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Anabasum has demonstrated positive results in two Phase 2 studies, one in diffuse cutaneous systemic sclerosis and one in cystic fibrosis. Additionally, anabasum is being evaluated in a 12-month open-label extension study in diffuse cutaneous systemic sclerosis, a Phase 2 study in skin-predominant dermatomyositis with a 12-month open-label extension, and soon in another Phase 2 study in systemic lupus erythematosus.

Corbus plans to commence a Phase 3 study to support a New Drug Application (NDA) of anabasum for the treatment of systemic sclerosis in the fourth quarter of 2017. The Company is also planning to initiate a larger and longer Phase 2b study of anabasum for the treatment of cystic fibrosis in the fourth 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.

Investor Contact
Jenene Thomas
Jenene Thomas Communications, LLC
Phone: +1 (908) 938-1475
Email: jenene@jenenethomascommunications.com

Media Contact
David Schull
Russo Partners, LLC
Phone: +1 (858) 717-2310
Email: david.schull@russopartnersllc.com

Source: Corbus Pharmaceuticals Holdings, Inc.