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Corbus Pharmaceuticals Announces Last Patient Enrolled in Phase 2 Study of Resunab for Systemic Sclerosis

Top-Line Phase 2 Data on Track for 4Q 2016

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[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 it has completed patient enrollment in its Phase 2 clinical trial of Resunab for the treatment of diffuse cutaneous [systemic sclerosis](#) ("systemic sclerosis"). The Company expects to report top-line results from this study in the fourth quarter of 2016.

Principal Investigator 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, commented, "We have long recognized the need for proven therapies for systemic sclerosis and were eager to participate in this clinical study of Resunab. Our hope is that treatment utilizing Resunab will lead to a reduction of inflammation and fibrosis without immunosuppression and without the need for patients to discontinue their other medications."

Corbus launched its Phase 2 clinical study of Resunab for the treatment of systemic sclerosis in August 2015. The multi-center, double-blind, randomized, placebo-control Phase 2 study is being conducted in the United States, and is designed to evaluate Resunab's efficacy, safety and tolerability in up to 44 individuals with systemic sclerosis. Efficacy is measured using the American College of Rheumatology's Combined Response Index for diffuse cutaneous Systemic Sclerosis (CRISS) which includes measurements of skin and lung involvement, patient disability, and patient and physician assessments of general health. This Phase 2 study is also evaluating multiple secondary endpoints, including Resunab's mechanism of action and effect on biomarkers in systemic sclerosis. Subjects in the study are treated with Resunab or placebo for 84 days with a follow-up period of 28 days.

"We are very pleased to have completed patient enrollment ahead of schedule in this Phase 2 study in systemic sclerosis. These patients suffer from serious morbidity and have a significant need for new effective treatments, especially those that don't suppress the immune system. We look forward to having the top-line data before the end of this year.

Additionally, we will be collecting data on safety and efficacy of Resunab in systemic sclerosis in the open-label extension phase of this study," stated Barbara White, M.D., Chief Medical Officer of Corbus.

Yuval Cohen, Ph.D., Chief Executive Officer of Corbus commented, "We are very pleased to have accomplished this clinical milestone for Corbus and are looking forward to completing the treatment phase of this study and releasing top-line data in the fourth quarter this year. We are grateful to the individuals, their families and physicians who are participating in the studies."

Resunab was granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of systemic sclerosis from the U.S. Food and Drug Administration ("FDA") in 2015. Corbus received [approval for an open-label extension to its Phase 2 Clinical Study of Resunab for systemic sclerosis](#) from the FDA in April of 2016. The open-label extension enables all the participants in the study to receive Resunab for an additional 12 months.

For more information on the Phase 2 study with Resunab 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 Resunab

Resunab 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 Resunab to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Resunab 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. Resunab has direct effects on fibroblasts to halt tissue scarring. In effect, Resunab 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, Resunab, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Resunab 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 trial 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 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: [Email contact](#)

Media Contact

David Schull
Russo Partners, LLC
Phone: +1 (858) 717-2310
Email: [Email contact](#)

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