

# Corbus Pharmaceuticals Announces Dosing of First Patient in Phase 2 Clinical Trial of Resunab(TM) for the Treatment of Dermatomyositis

NORWOOD, MA -- (Marketwired) -- 07/13/15 -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, and serious inflammatory and fibrotic diseases, announced today that patient dosing has commenced in a Phase 2 clinical study of its investigational drug Resunab TM for the treatment of skin-predominant dermatomyositis.

The first patient was dosed by the principal investigator of the study, Victoria P. Werth, M.D., Professor of Dermatology and Medicine at the University of Pennsylvania School of Medicine and Chief, Dermatology, Corporal Michael J. Crescenz VAMC (Philadelphia). The Resunab trial in dermatomyositis is funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania School of Medicine and is expected to be completed in early 2017.

"I am very pleased this Phase 2 study is now underway," Dr. Werth commented. "Unfortunately, in the United States there are no FDA-approved treatments specific to dermatomyositis, and many patients have persistent disease with the currently available therapies. Based on its favorable safety profile and mechanism of action in pre-clinical and prior clinical studies, I believe Resunab may offer the potential to safely and effectively address a huge unmet medical need for individuals with skin-predominant dermatomyositis."

Dermatomyositis, a rare, inflammatory muscle disease accompanied by skin rashes, affects up to approximately 25,000 individuals in the United States. The pathology can involve serious pulmonary, cardiovascular, and gastrointestinal systems, has a significant burden of illness, and impairs daily functioning and quality-of-life. There are currently no FDA-approved therapies specific to dermatomyositis, and physicians commonly treat manifestations of the disease with immunosuppressive therapies that have significant toxicities.

Barbara White, M.D., Chief Medical Officer of the Company, added, "The dosing of the first subject in this dermatomyositis trial marks an important milestone in our Resunab clinical development program. This is the start of testing Resunab for its ability to provide clinical benefit through resolution of chronic, refractory skin inflammation. Corbus is honored to have this opportunity to work with Dr. Werth, the University of Pennsylvania, the Veterans

Administration Medical Center (Philadelphia) and the NIH on this program."

The Phase 2 trial will test safety, tolerability, clinical efficacy, biomarkers, and mechanism of action of Resunab in 22 adult subjects whose skin-predominant dermatomyositis is refractory to standard-of-care. Patients will receive oral Resunab or placebo once a day for 28 days, then twice a day for the next 56 days, for a total treatment duration of 84 days, with 28 days follow-up.

For more information on the Phase 2 study with Resunab for the treatment of dermatomyositis, please visit ClinicalTrials.gov and reference Identifier NCT02466243.

# About Dermatomyositis

Dermatomyositis is a rare autoimmune disease of unknown etiology that is characterized by inflammation and subsequent damage to muscles and skin. People of any race, age, or gender can be afflicted by dermatomyositis, but it most commonly occurs in children and in adults age 50 to 70. Women develop dermatomyositis more often than men. Muscle inflammation can cause weakness, and create difficulty walking, lifting objects, climbing stairs, or swallowing. Skin involvement typically includes a distinctive reddish-purple rash on the upper eyelids, across the cheeks and bridge of the nose in a "butterfly" distribution; and scaling and changes of affected skin on the knuckles, elbows, knees, and other regions. Patients with dermatomyositis can develop interstitial lung disease and heart inflammation, which can be life-threatening, and their risk of developing cancer is increased. Dermatomyositis has a significant impact on day-to-day functioning of the patients and quality of life. Up to approximately 25,000 people in the United States suffer from this disease. There are currently no FDA-approved therapies specific to dermatomyositis.

# About Resunab ™

Resunab <sup>™</sup> is a novel synthetic oral drug that is a preferential agonist to the CB2 receptor expressed on activated immune cells. CB2 activation triggers endogenous pathways that resolve inflammation and halt fibrosis. Pre-clinical and Phase 1 studies have shown Resunab to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in pre-clinical models of inflammation and fibrosis. Resunab triggers resolution of inflammation by increasing production of "Specialized Proresolving Lipid Mediators of Inflammation" and anti-inflammatory mediators, while reducing production of pro-inflammatory mediators and reducing the numbers of immune cells in affected tissues. 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 <sup>™</sup> is a novel oral drug that resolves chronic inflammation and fibrotic processes. Resunab is scheduled to commence Phase 2 clinical trials for the treatment of cystic fibrosis and diffuse cutaneous systemic sclerosis ("scleroderma") in 2015. In July 2015, we initiated a Phase 2 clinical trial of Resunab in skin-predominant dermatomyositis funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania School of Medicine. For more

information, please visit www.CorbusPharma.com.

### 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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