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Corbus Pharmaceuticals Announces Addition of Phase 2 Clinical Protocol for Resunab Treatment of Systemic Lupus Erythematosus to FDA IND

Important Regulatory Step for Initiation of Multicenter SLE Trial Funded by National Institutes of Health (NIH)

NORWOOD, MA -- (Marketwired) -- 03/31/16 --

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 a protocol amendment has been added to one of the Company's existing Investigational New Drug ("IND") Application with the U.S. Food and Drug Administration ("FDA") for a Phase 2 clinical trial of Resunab in systemic lupus erythematosus ("SLE"). The amendment was filed on February 25, 2016. The addition of the SLE Phase 2 trial to the existing Resunab IND is an important step towards the initiation of the 100 patient, double-blind, placebo-controlled SLE trial which will be funded by a grant from the National Institutes of Health ("NIH") to the Feinstein Institute for Medical Research ("FIMR"), Manhasset. The Company expects the trial will commence in the first quarter of 2017.

Resunab is a novel synthetic endocannabinoid-mimetic drug that we believe has the potential to resolve widespread inflammation associated with active SLE, and, in particular, inflammation of the musculoskeletal system. The Phase 2 SLE trial will evaluate Resunab at 5 mg, 20 mg, and 20 mg twice daily, administered orally for 84 days, with 28 days follow-up, at approximately ten U.S. sites. The primary outcome assesses pain from active musculoskeletal disease and secondary efficacy outcomes include assessments of overall disease activity using standard SLE Disease Activity Index ("SLEDAI") and British Isles Lupus Activity Group ("BILAG") scoring systems in SLE. Resunab is currently being evaluated in three on-going Phase 2 clinical trials for the treatment of cystic fibrosis, systemic sclerosis, and dermatomyositis

"The support from the NIH's Autoimmunity Centers of Excellence to FIMR and Meggan Mackay, M.D., M.S., Principal investigator in this Phase 2 trial, is invaluable to the expansion of the clinical testing of Resunab into another serious autoimmune disease," stated Barbara White, M.D., Chief Medical Officer of Corbus. "Resunab has a novel mechanism of action and is designed to trigger endogenous pathways to turn off chronic inflammation and fibrotic

processes, without causing immunosuppression. Based on the existing clinical safety data and the pre-clinical efficacy data, we see an opportunity for Resunab to provide therapeutic benefits to individuals living with SLE."

Dr. Mackay added, "Corticosteroids or other immunosuppressive therapies are commonly used by physicians to treat patients with SLE who have active musculoskeletal disease that is refractory to anti-malarial agents and NSAIDS. Because these treatments can have major toxicities, there remains a significant unmet medical need in the treatment of SLE. I believe Resunab has the potential to treat active musculoskeletal disease and overall disease activity in SLE."

About Systemic Lupus Erythematosus

Systemic lupus erythematosus is a prototypical autoimmune disease in which the innate immune system is chronically activated by immune complexes containing autoantibodies and self-antigens, which leads to widespread inflammation and tissue damage. SLE typically occurs more often in women than men and is most common between the ages 15 to 35. According to the CDC, SLE affects between 161,000 - 322,000 people in the United States and about 500,000 people worldwide. SLE has many manifestations, including arthritis, rash, photosensitivity, oral ulcers, pleuritis, pericarditis, kidney problems, seizures and psychosis and blood cell abnormalities. The musculoskeletal system is the most commonly involved system in SLE. The pathology of SLE involves chronic activation of the innate immune system by immune complexes, with activation of complement, increased production of type 1 interferons and other mediators of inflammation and resultant tissue inflammation and damage. Patients with SLE have an increased frequency of related autoimmune problems, such as Sjogren's syndrome and antiphospholipid syndrome that require additional treatments. SLE may occur with other autoimmune conditions, such as thyroiditis, hemolytic anemia, and idiopathic thrombocytopenia purpura. Accelerated atherosclerosis among SLE patients is responsible for premature mortality. Drugs specifically approved by the FDA for SLE are limited to aspirin, corticosteroids, hydroxychloroquine and belimumab. Physicians commonly treat disease manifestations with immunosuppressive or corticosteroid therapies that have significant toxicities.

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. 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 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 pro-inflammatory eicosanoids and cytokines. 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, bacterial infections, and fibrotic processes. Resunab is currently in Phase 2 clinical studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis, skin-predominant dermatomyositis and systemic lupus erythematosus.

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.

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