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Corbus Pharmaceuticals' Investigational Drug Resunab(TM) Granted Fast Track Status by the U.S. FDA for the Treatment of Systemic Sclerosis

NORWOOD, MA -- (Marketwired) -- 08/19/15 -- 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 the U.S. Food and Drug Administration ("FDA") has designated as a Fast Track development program the investigation of Resunab™ for systemic sclerosis ("scleroderma").

Systemic sclerosis is a serious, life-threatening autoimmune disease that is characterized by chronic activation of the immune system, damage to blood vessels, and fibrosis (scarring) of the skin, lungs, and other internal organs. Systemic sclerosis affects predominately women in mid-life and is associated with significant morbidity and mortality. There are currently no FDA-approved drug therapies for systemic sclerosis.

Resunab is a novel synthetic oral endocannabinoid-mimic drug that preferentially binds to a receptor called CB2 on immune cells and fibroblasts. Numerous pre-clinical and ex-vivo models have demonstrated that the binding of Resunab to CB2 triggers the production of "Specialized Pro-resolving Lipid Mediators" ("SPMs") that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis. This resolution cascade restores chronically activated immune systems back to homeostasis and halts fibrosis, without causing immunosuppression.

"We are very pleased to have achieved another significant regulatory milestone for Resunab for the treatment of systemic sclerosis, following the recently granted FDA Orphan Drug Designation in this indication," said Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. "With Fast Track status, we expect to have the opportunity to accelerate Resunab's clinical development timeline to more expediently bring this potentially impactful drug therapy to individuals with systemic sclerosis."

A Fast Track designation enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

Corbus is scheduled to begin enrollment and dosing in its Phase 2 study of Resunab for the treatment of systemic sclerosis this quarter. For more information on this study, please visit ClinicalTrials.gov and reference Identifier NCT02465437.

About Resunab™

Resunab™ 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 Pro-resolving Lipid Mediators of Inflammation" and anti-inflammatory mediators, while reducing production of pro-inflammatory mediators and tissue inflammation. 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 oral drug that resolves chronic inflammation and fibrotic processes. Resunab is currently in Phase 2 studies for the treatment of diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis. A Phase 2 clinical trial with Resunab for the treatment of cystic fibrosis is scheduled to commence in 2015.

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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