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# Corbus Pharmaceuticals Announces FDA Orphan Drug Designation for Resunab(TM) for the Treatment of Systemic Sclerosis (Scleroderma)

NORWOOD, MA -- (Marketwired) -- 06/12/15 -- [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 granted Corbus' lead drug candidate [Resunab](#)<sup>™</sup> Orphan Drug Designation for the treatment of [systemic sclerosis](#).

Systemic sclerosis is a chronic, serious, life-threatening inflammatory disease causing fibrosis of skin and internal organs, affecting predominately women in mid-life. Systemic sclerosis is associated with severe morbidity and high mortality. There are currently no FDA-approved drug therapies for systemic sclerosis.

"We are very pleased to receive FDA Orphan Drug Designation for Resunab in systemic sclerosis. This is an important regulatory milestone for the company and a significant step forward in our clinical development of Resunab targeting this rare disease associated with such a critical unmet need for safe and effective therapeutics," stated Yuval Cohen, Ph.D., Chief Executive Officer of the Company. "Based on its novel mechanism of action of triggering the inflammatory resolution pathway, we believe Resunab has the potential to become an important therapy for systemic sclerosis patients as well as other diseases in which chronic inflammation and fibrosis persist."

Resunab is a novel synthetic oral drug that has the potential to treat chronic inflammation and fibrosis. Pre-clinical and Phase 1 studies have shown Resunab to have a favorable safety, tolerability and pharmacokinetic profile. The FDA has already cleared the Corbus' investigational new drug application ("IND") for systemic sclerosis and the Company is preparing to commence Phase 2 studies.

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent so-called orphan diseases and disorders that affect fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period against competition, as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees.

***About Scleroderma***

Systemic sclerosis is a chronic, systemic autoimmune rheumatic disease with an unclear etiology. Systemic sclerosis affects around 70,000 people in the United States, with disease onset typically in mid-life. About 80 percent of sclerosis patients are women. The disease process in systemic sclerosis includes damage to small blood vessels and activation of the immune system, leading to chronic tissue inflammation and fibrosis of the skin and internal organs, including the lungs, heart, kidneys, gastrointestinal tract, and musculoskeletal system. Chronic disease burden, morbidity and mortality are significant. About four or five of every ten patients in the United States with systemic sclerosis die within 10 years of disease onset, usually from cardiopulmonary disease such as restrictive (fibrotic) lung disease, pulmonary hypertension or sudden death. Immunosuppressive medications such as oral corticosteroids are commonly used to treat these patients, and there are no FDA-approved treatments for systemic sclerosis.

### ***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 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 Pharmaceuticals***

Corbus Pharmaceuticals 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 scheduled to commence Phase 2 clinical trials for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis ("scleroderma"), and skin-predominant dermatomyositis in 2015. For more information, please visit [www.CorbusPharma.com](http://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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