

Corbus Pharmaceuticals Receives FDA Orphan Drug Designation for Lenabasum for the Treatment of Dermatomyositis

- Dermatomyositis is a rare chronic systemic autoimmune disease characterized by inflammation of muscles and skin
- DM affects ~80,000 in the US, EU and Japan and has a 5-year mortality rate as high as 30%

Norwood, MA, July 20, 2018 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic and serious inflammatory and fibrotic diseases, announced today that the U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation ("ODD") to lenabasum, its novel, synthetic oral endocannabinoid-mimetic drug, for the treatment of dermatomyositis ("DM").

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent 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 Dermatomyositis

Dermatomyositis is a rare and serious systemic autoimmune condition characterized by skin and muscle involvement. Like other autoimmune diseases, it affects more women than men and morbidity is more severe in black, Asian and Native American populations. The disease is characterized by distinct skin lesions that can be accompanied by erosions, photosensitivity, itch, ulcers, calcinosis and hair loss as well as other abnormalities. Muscle inflammation and atrophy is a characteristic of the disease and can manifest as weakness. Dermatomyositis affects as many as 80,000 people in the US, EU and Japan. Mortality is high with 5-year survival of 70% and 10-year survival of 57%. Standard of care includes antimalarial drugs and potent immunosuppressive agents, which often lead to significant adverse effects.

About Lenabasum

Lenabasum is a synthetic, oral, small-molecule, selective cannabinoid receptor type 2 (CB2)

agonist that preferentially binds to CB2 expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. CB2 activation also induces the production of specialized proresolving lipid mediators that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory mediators. Through activation of CB2, lenabasum also is designed to have a direct effect on fibroblasts to halt tissue scarring. Lenabasum is believed to induce resolution rather than immunosuppression by triggering biological pathways to turn "off" chronic inflammation and fibrotic processes. Lenabasum has demonstrated promising potency in preclinical models of inflammation and fibrosis. Preclinical and human clinical studies have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Further, the drug has demonstrated clinical benefit and positive impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. The Company's lead product candidate, lenabasum, is a novel, synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis, and systemic lupus erythematosus.

For more information, please visit <u>www.CorbusPharma.com</u> and connect with the Company on <u>Twitter</u>, <u>LinkedIn</u>, <u>Google+</u> and <u>Facebook</u>.

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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