September 18, 2018

Corbus Pharmaceuticals Receives Orphan Designation for Lenabasum for the Treatment of Dermatomyositis in the European Union

– 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, Sept. 18, 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 European Commission has granted Orphan Designation in the European Union ("EU") to lenabasum, its novel, synthetic oral endocannabinoid-mimetic drug, for the treatment of dermatomyositis ("DM").

The Company recently announced that lenabasum was also granted Orphan Drug Designation ("ODD") for the treatment of DM by the U.S. Food and Drug Administration ("FDA").

Orphan Designation is granted by the European Commission to drugs that are intended for the treatment, prevention or diagnosis of life-threatening or chronically debilitating rare diseases where no satisfactory method of diagnosis, prevention or treatment of the condition concerned is authorized. If such a method exists, then the medicine must be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of not more than five per 10,000 population in the EU. The Orphan Designation provides potential incentives for the sponsor to develop a medicine for a rare disease, such as protocol assistance, reduced fees, funding for clinical trials, and protection from competition in the EU once the medicine is placed on the market, including ten years of market exclusivity.

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 (formerly known as anabasum) is a synthetic, oral, small-molecule, selective cannabinoid receptor type 2 (CB2) agonist that has been shown to preferentially bind to CB2 expressed on activated immune cells and fibroblasts in animal studies. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. CB2 activation also induces 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 multiple inflammatory mediators. Through activation of CB2, lenabasum also is believed to have a direct effect on fibroblasts to halt tissue scarring. In preclinical and clinical studies conducted so far, lenabasum has been shown 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 data and clinical studies to date have shown lenabasum to have a favorable safety, tolerability and pharmacokinetic profile. Data to date suggest that the drug may have clinical benefit as well as a beneficial impact on inflammatory and immunological markers in Phase 2 studies in diffuse cutaneous systemic sclerosis, dermatomyositis and cystic fibrosis. Additional clinical studies are being conducted and/or planned to confirm these preliminary results and support applications for regulatory approval.

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 www.CorbusPharma.com and connect with the Company on Twitter, LinkedIn, 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.

Source: Corbus Pharmaceuticals Holdings, Inc.

Investor Contacts:

Institutional Investor Inquiries
Ted Jenkins, Senior Director, Investor Relations and Communications
Corbus Pharmaceuticals, Inc.
Phone: +1 (617) 415-7745
Email: ir@corbuspharma.com

All Other Investor Inquiries
Jenene Thomas
Jenene Thomas Communications, LLC
Phone: +1 (833) 475-8247
Email: crbp@jtcir.com

Media Contact
Eliza Schleifstein
Scient Public Relations
Phone: + 1 (917) 763-8106
Email: eliza@scientpr.com

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