

January 3, 2019



Corbus Pharmaceuticals Announces Strategic Collaboration with Kaken Pharmaceutical Co., Ltd. to Develop and Commercialize Lenabasum in Japan for Systemic Sclerosis and Dermatomyositis

- *Collaboration in-line with Corbus vision to become the global leader in the treatment of inflammatory and fibrotic diseases by targeting the endocannabinoid system*
- *Advances strategy to partner lenabasum commercial rights outside US and EU*
- *Japan presents important market with 28,000 SSc patients and 9,000 DM patients and no currently approved drugs*

Norwood, MA, and Tokyo, Japan, Jan. 03, 2019 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company") announced today that they have entered into a strategic collaboration with Kaken Pharmaceutical Co., Ltd. ("Kaken") for the development and commercialization in Japan of Corbus' investigational drug lenabasum for the treatment of systemic sclerosis ("SSc") and dermatomyositis ("DM"), two rare and serious autoimmune diseases.

Under the terms of the agreement, Kaken receives an exclusive license to commercialize and market lenabasum in Japan for systemic sclerosis and dermatomyositis. Kaken will make an upfront payment to Corbus of \$27 million. Corbus will be eligible to receive in addition up to \$173 million upon achievement of certain regulatory, development and sales milestones as well as double-digit royalties.

Current patient numbers for systemic sclerosis and dermatomyositis¹ in Japan are 28,000 and 9,000, respectively.

"We are honored to collaborate with Kaken, a company that shares our passion and dedication to working together to bring to market novel therapies targeting serious rare inflammatory diseases," said Yuval Cohen, PhD., Chief Executive Officer of Corbus. "Kaken is a well-regarded leader in rare autoimmune diseases in Japan with a proud history of scientific and medical innovation. By working together, we believe we can expand the Japanese footprint for lenabasum alongside Corbus' ongoing efforts in the U.S. and E.U. This collaboration is an important next step in achieving our vision of becoming the global leader in treating inflammatory diseases by focusing on the endocannabinoid system."

“It is my pleasure to start a collaboration with Corbus, a company with a strong passion toward developing novel therapeutics for rare autoimmune diseases,” said Tetsuo Onuma, President and Representative Director of Kaken. “With this collaboration, we hope we can further contribute for the better lives of patients with rare autoimmune disease in Japan.”

About Lenabasum

Lenabasum is a rationally-designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2). CB2 is preferentially expressed on activated immune cells, fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to-date, lenabasum has induced the production of Specialized Pro-resolving lipid Mediators (“SPMs”) that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Lenabasum is also believed to have a direct effect on fibroblasts to limit production of fibrogenic growth factors and extracellular connective tissue that lead to tissue fibrosis (scarring). Data from animal models and human clinical studies suggest that lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. Lenabasum has demonstrated promising activity in animal models of skin and lung inflammation and fibrosis in systemic sclerosis (SSc). Lenabasum is also active in animal models of lung infection and inflammation in cystic fibrosis and joint inflammation and scarring in rheumatoid arthritis.

Lenabasum has demonstrated favorable safety and tolerability profiles in clinical studies to date. Lenabasum improved multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and skin-predominant dermatomyositis. Lenabasum also reduced pulmonary exacerbations in a Phase 2 cystic fibrosis study. Additional clinical studies are being conducted and/or planned to confirm these 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 inflammatory and fibrotic diseases by leveraging its pipeline of endocannabinoid system-targeting synthetic drug candidates. The Company's lead product candidate, lenabasum, is a novel, synthetic, oral, selective cannabinoid receptor type 2 (CB2) agonist designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis, and systemic lupus erythematosus.

Corbus licensed the exclusive worldwide rights to develop, manufacture and market drug candidates from more than 600 novel compounds targeting the endocannabinoid system from Jenrin Discovery LLC. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to eliminate blood-brain barrier penetration and subsequent brain CB1 receptor occupancy that mediates the neuropsychiatric adverse events associated with first-generation CB1 inverse agonists. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction and acute interstitial nephritis, among others. Corbus plans to enter a Phase 1 study of CRB-4001 in 2019, intended to be followed by a National Institutes of Health (NIH)-funded proof-of-concept Phase 2 study.

For more information, please visit www.CorbusPharma.com and connect with the Company on Twitter, LinkedIn, and Facebook.

About Kaken

Kaken (Tokyo Stock Exchange: 4521) is a specialty pharmaceutical company in Japan with strong experience in developing and commercializing novel pharmaceuticals and medical devices in the fields of orthopedics, dermatology and surgery. Kaken concentrates its R&D resources in inflammation/immunology (dermatitis, rheumatoid arthritis and osteoarthritis), pain relief and fungal infection areas. For more information, please visit <http://www.kaken.co.jp/english/>

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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¹ Health Advances, LLC; Lenabasum Commercial Market Assessment



Source: Corbus Pharmaceuticals Holdings, Inc.