

Lenabasum Open-Label Extension Data to be Presented at EULAR 2019 Continue to Show a Favorable Safety Profile and Improvement in Efficacy Outcomes in Systemic Sclerosis and Dermatomyositis Phase 2 Studies

- ACR CRISS score remains ≥ 0.95 (95%) at 21 months in systemic sclerosis open-label extension (OLE) study
- CDASI activity score reaches -21.8 points at 16 months in dermatomyositis OLE study
- 81% systemic sclerosis subjects remain on lenabasum in the OLE ≥ 21 months; 90% dermatomyositis subjects remain in OLE at ≥ 16 months
- No serious or severe AEs related to lenabasum reported in these studies to date
- Systemic sclerosis and dermatomyositis are rare and serious autoimmune diseases affecting ~280,000 people total in the U.S., EU and Japan
- Corbus continues to be a pioneer in the development of transformative medicines that target the endocannabinoid system

Norwood, MA, June 12, 2019 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company") today announced continued favorable safety and durable improvement in efficacy outcomes at 21 months compared to 12 months in open-label extensions (OLE) of lenabasum Phase 2 studies in two rare and serious autoimmune diseases: systemic sclerosis (SSc) and dermatomyositis (DM). These data are being presented at the annual European Congress of Rheumatology (EULAR 2019) conference being held June 12-15, 2019 in Madrid.

"Lenabasum treatment has been safe and well tolerated to date in studies JBT101-SSc-001 and JBT101-DM-002, including some subjects who have received lenabasum for more than two years. These findings support the potential for lenabasum to be used as a chronic treatment," said Barbara White, M.D., Chief Medical Officer of the Company. "We are encouraged by the degree, durability, and consistency of improvement in multiple efficacy outcomes in subjects in both of these Phase 2 SSc and DM open label extension studies."

Safety & Efficacy Outcomes in Systemic Sclerosis (SSc):

• Durable improvement was observed in the ACR CRISS score, which remained ≥ 0.95 from month 12 through month 21 in the OLE, and in change in mRSS, which

improved \geq 9.8 points during the same time. An ACR CRISS score of \geq 0.60 (60%) has been reported to be medically important, as has an improvement of -4 to -5 points in mRSS.

- 81% of subjects were still enrolled in the OLE at month 21.
- Patient and physician global assessments of health, skin symptoms, itch, and patientreported disability and function showed either stabilization or increasing improvement during the OLE from month 12 through 21.
- Mean FVC % predicted declined -3.2% from study start through latest data cut in March 2019.
- No severe AEs or study discontinuations related to lenabasum to date in these studies.
- 35 of 36 subjects (97%) had ≥ 1 AE during ≥ 21 months dosing the OLE, for a total of 249 AEs in the OLE through March 5, 2019.
- Seven serious AEs, all unrelated to lenabasum, occurred in 5 of 36 subjects (14%): 1 each of scleroderma renal crisis, thrombocytopenic microangiopathy, iron deficiency anemia, multiple fractures, herpes zoster; and 2 AEs each of ischemic digital ulcers.
- AEs leading to study discontinuation, both unrelated to lenabasum, occurred in 2 of 36 subjects (6%): tendonitis and scleroderma renal crisis.
- AEs possibly related to lenabasum occurred in 4 of 36 subjects (11%). Three of 36 subjects (8%) had AEs judged to be probably or definitely related to lenabasum: 1 had mild fatigue, 1 had a moderate skin ulcer and moderate lymph node pain, and 1 had mild disturbance in attention, mild lethargy, and moderate feeling abnormal.

Efficacy and safety of lenabasum in SSc is currently being evaluated in the Company's international, multicenter RESOLVE-1 Phase 3 study, with data expected in the summer of 2020. Lenabasum has been granted Orphan Drug Designation and Fast Track designation for the treatment of SSc from the FDA and Orphan Designation for the treatment of SSc from the EMA. Lenabasum is not approved for the treatment of systemic sclerosis.

Safety & Efficacy Outcomes in Dermatomyositis (DM):

- The Cutaneous Dermatomyositis Activity and Severity Index (CDASI) activity score continued to improve in the OLE with a mean improvement of -21.8 points at month 16.
 An improvement of -4 to -5 points in CDASI activity score is considered medically important.
- 90% of subjects were still enrolled in the OLE at month 16.
- An increasing number of subjects (67%) reached low disease activity at month 16, with CDASI activity score ≤ 14.
- Continued improvement or stable improvement from month 12 to month 16 was observed during the OLE in patient- and physician-reported global disease activity, physician assessment of extra-muscular disease activity, patient-reported global assessment of skin activity, skin symptoms, itch, hair loss, and pain.
- No serious AEs and no AEs leading to study discontinuation occurred.
- 100% of 20 subjects had ≥ 1 AE during ≥ 16 months dosing the OLE, for a total of 76 AEs in the OLE through March 5, 2019.
- AEs possibly related to lenabasum occurred in 7 (35%) subjects. One (5%) had a mild AE of fatigue judged to be probably related to lenabasum.
- Lenabasum treatment was associated with a reduction in skin biopsies of CD4+ T cells, CB2 expression by T cells, interferon-β and IFN-gamma mRNA and protein expression, IL-31 and CB2 protein expression in DM.

Efficacy and safety of lenabasum in DM is currently being evaluated in the Company's international, multicenter <u>DETERMINE</u> Phase 3 study. Lenabasum has been granted Orphan Drug Designation for the treatment of DM from the FDA and EMA. Lenabasum is not approved for the treatment of dermatomyositis.

About Lenabasum

Lenabasum is a rationally-designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2) and has been designed to resolve inflammation, limit fibrosis and support tissue repair. CB2 is preferentially expressed on activated immune cells and also on fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to date, lenabasum has induced the production of pro-resolving lipid mediators that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. 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 an acceptable safety and tolerability profiles in clinical studies to date. Lenabasum treatment was associated with improvement in multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and patients with DM with active skin involvement but not currently active muscle involvement. Lenabasum treatment also was associated with a lower rate of and longer time to pulmonary exacerbations in a Phase 2 cystic fibrosis study. Additional clinical studies are being conducted to confirm these results and support applications for regulatory approval.

About Systemic Sclerosis

Systemic sclerosis (SSc), a form of scleroderma, is a chronic, rare systemic autoimmune disease affecting approximately 200,000 people in the U.S., EU and Japan. SSc is more common in adults and women than in men and children, and typically occurs in people aged 30 to 50 years old. The disease is characterized by chronic inflammation, fibrosis (for example, scarring) and small blood vessel damage in multiple organs in the body. Scleroderma is an autoimmune disease, but it is unknown why the body's immune system is activated and stays active, damaging the body's own tissue. SSc has the highest mortality rate among the systemic autoimmune diseases. There is no cure for systemic sclerosis, and there are no FDA-approved treatments for this disease.

About Dermatomyositis

Dermatomyositis (DM), a form of myositis, is a chronic, rare systemic autoimmune disease affecting approximately 80,000 people in the U.S., EU and Japan.¹ The disease is typically diagnosed when a person is between 50 and 60 years old, and women are more commonly affected than men.^{7,8} DM is characterized by skin rash and muscle weakness, alone or together. DM is caused by chronic activation of the immune system, which causes inflammation in the skin, the muscles and other organs, damaging these body parts.

There is no cure for DM, a disease that continues to progressively worsen over time. 9,10 Typically, people with DM are prescribed drugs that suppress the immune system. These treatments may be associated with significant side effects, such as serious infections. 11 FDA-approved treatments for DM include systemic corticosteroids and adrenocorticotropic hormone analogue. 12,13

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 is also developing a pipeline of drug candidates from more than 600 novel compounds targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, peripherally-restricted, selective cannabinoid receptor type 1 (CB1) inverse agonist. Potential indications for CRB-4001 include NASH, among others. Corbus plans to start 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 <u>www.CorbusPharma.com</u> 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.

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Source: Corbus Pharmaceuticals Holdings, Inc.

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