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Corbus Pharmaceuticals Announces Change of Primary Endpoint in Ongoing RESOLVE-1 Phase 3 Study in Systemic Sclerosis in U.S. to ACR CRISS from mRSS Following Meeting with FDA

- *Phase 3 primary endpoint will now be aligned with that of previous Phase 2 study*
- *ACR CRISS is a composite index (composed of multiple outcomes including mRSS) and was secondary endpoint in current Phase 3 study*
- *Change in mRSS will become secondary endpoint*
- *No changes to conduct or size of Phase 3 study; study remains on track for completion in the first half of 2020*

Norwood, MA, April 18, 2019 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company") today announced that following a Type C meeting with the U.S. Food and Drug Administration (FDA), Corbus will change the primary efficacy endpoint of the ongoing RESOLVE-1 Phase 3 trial for systemic sclerosis (SSc) in the U.S. to the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) score at Week 52 from the current primary endpoint, change in modified Rodnan Skin core (mRSS). The ACR CRISS score was the primary efficacy endpoint of the Phase 2 study evaluating lenabasum for the treatment of diffuse cutaneous SSc. The Company remains on track to complete the RESOLVE-1 study in the first half of 2020 and no changes to the size or length of the study are required.

The ACR CRISS score provides a comprehensive measure of response to treatment compared to mRSS, which only measures skin thickening. The ACR CRISS score is calculated from weighted changes from baseline in five core outcome measures commonly used to evaluate treatment effect in trials for SSc: mRSS, Health Assessment Questionnaire - Disability Index (HAQ-DI), forced vital capacity (FVC) percent predicted, and patient and physician global assessments of health related to SSc.

"Following a recent Type C meeting with the FDA, we will be designating the ACR CRISS score as the primary efficacy endpoint for the current RESOLVE-1 Phase 3 study in the U.S. In that meeting, the FDA recognized the unmet medical needs of SSc patients, challenges in developing drugs to treat SSc and limitations of current endpoints for trials in SSc. The FDA deferred selection of the primary efficacy endpoint to Corbus. The FDA stated that the

components of ACR CRISS reflect relevant aspects of SSc, and they will consider the totality of the data during review of any marketing application in SSc. We will pursue discussions with other regulatory authorities to consider changing primary efficacy outcome to ACR CRISS outside of the U.S.," said Barbara White, M.D., Chief Medical Officer of Corbus.

Dr. White continued, "We believe that using the ACR CRISS score as the primary efficacy endpoint increases our probability of success in the RESOLVE-1 study in the U.S. The ACR CRISS score has proven more sensitive to treatment effect than mRSS in recent trials, and we saw an encouraging treatment effect with lenabasum compared to placebo in our Phase 2 study using this endpoint. ACR CRISS has received provisional endorsement by the American College of Rheumatology as an outcome measure for interventional trials in diffuse cutaneous SSc and its use as the primary efficacy endpoint in our Phase 3 study was recommended by the study's Steering Committee. We believe the study is well powered for this primary endpoint and subject numbers, visits, and assessments of the core items needed to calculate the ACR CRISS scores will continue unchanged from what is currently in the Phase 3 protocol."

In the U.S., trial protocol and the first and third secondary efficacy endpoints of RESOLVE-1 (i.e., changes in HAQ-DI and FVC percent predicted, respectively) remain unchanged. Change in mRSS will become the second secondary efficacy endpoint. Corbus remains blinded to the treatment assignment of subjects until after database lock occurs in the first half of 2020.

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 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 skin-predominant dermatomyositis. ACR CRISS score was the primary efficacy endpoint in the Phase 2 study of lenabasum in diffuse cutaneous SSc and showed a greater treatment effect in subjects who received lenabasum compared to placebo in that study. 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 and/or planned 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.[1] SSc is more common in adults and women than in men and children, and typically occurs in people aged 30 to 50 years old.[2] The disease is characterized by chronic inflammation, fibrosis (for example, scarring) and small blood vessel damage in multiple organs in the body.[3] 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.[4] SSc has the highest mortality rate among the systemic autoimmune diseases.[5] There is no cure for systemic sclerosis, and there are no FDA-approved treatments for this disease.[6]

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 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.

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Source: Corbus Pharmaceuticals Holdings, Inc.