

October 22, 2018



Corbus Pharmaceuticals Presents Lenabasum Long-Term Open-Label Clinical Data Showing Maintenance of Favorable Safety Profile and Further Improvement in Multiple Efficacy Endpoints in Systemic Sclerosis and Dermatomyositis Phase 2 Studies

- *Lenabasum is a first-in-class novel, synthetic oral cannabinoid designed to treat rare, serious autoimmune diseases*
- *Favorable safety and tolerability profiles maintained with long-term chronic dosing*
- *Further improvement in key efficacy outcomes shows strength and durability of therapeutic effect*
- *Mean improvement in mRSS reaches -10.7 points and median ACR CRISS score reaches 99% at 18 months in SSc open-label extension study (OLE)*
- *Mean improvement in CDASI activity score reaches -17.6 points at 12 months in DM OLE study*
- *Two orphan diseases with ~280,000 patients in US, EU and Japan associated with high morbidity and significant mortality*

Norwood, MA, Oct. 22, 2018 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company with the industry's leading pipeline focused on treating inflammatory and fibrotic diseases by targeting the endocannabinoid system, today announced continued favorable safety and tolerability profiles and further improvement in efficacy outcomes in open-label extensions (OLEs) of lenabasum Phase 2 studies in two rare and serious autoimmune diseases, systemic sclerosis (SSc) and dermatomyositis (DM). Eighteen-month data from the SSc OLE and 12-month data from the DM OLE are being presented at the American College of Rheumatology (ACR) 2018 Annual Meeting in Chicago.

"We are very enthusiastic about the therapeutic potential of lenabasum in systemic sclerosis and dermatomyositis. In these ongoing open-label extension studies, lenabasum continues to have an acceptable safety and a promising efficacy profile consistent across time, multiple outcomes, and across the two related diseases," Barbara White, M.D., Chief Medical Officer of the Company, stated. "We look forward to completing our late-stage ongoing clinical

development program.”

Yuval Cohen, PhD, Chief Executive Officer of Corbus, added, “This latest long-term clinical data further strengthens our belief that specifically targeting the body’s endocannabinoid system (ECS) with rationally-designed synthetic cannabinoids could provide an entirely new way of treating not only these two devastating autoimmune diseases but a wide range of other chronic autoimmune and inflammatory diseases. With the recent addition of over 600 novel ECS-targeting compounds to our pipeline, Corbus is well positioned to leverage our expertise and proprietary intellectual property to carry out our vision of becoming a leader in this field.”

Safety

No severe or serious adverse events (AEs) related to lenabasum have occurred to date, with 100% DM subjects and 83% SSc subjects still enrolled in OLEs at 12 and 18 months, respectively. Lenabasum-related AEs occurring in more than 1 subject during chronic dosing were fatigue (n = 2, 10%) in DM OLE and dizziness (n = 2, 6%) in SSc OLE.

Efficacy Outcomes in SSc

- Further improvement in skin thickening (fibrosis) from study start was observed using the modified Rodnan Skin Score (mRSS), reaching -8.4 points at 6 months, -9.8 points at 12 months, and -10.7 points at 18 months. An improvement of -4 to -5 points in mRSS is considered medically important, and 87% of subjects had an improvement in mRSS of at least -5 points and 60% had an improvement in mRSS of at least -10 points at 18 months in the OLE.
- Continued improvement in overall disease was observed in SSc subjects using a composite outcome, the ACR CRISS score, which increased from a median of 0% at the start of the SSc OLE to 65% at 6 months to 77% at 12 months, then 99% at 18 months. A CRISS score of about 60% has been reported to be medically important, and 75% of subjects had a CRISS score of 60%, and 50% had a score of 100% at 18 months.
- Measures of patient global health, skin symptoms, itch, and patient-reported disability and function all improved during the SSc OLE, with improvement increasing throughout the OLE or stabilizing from months 12-18. 83% of subjects who entered the OLE remained in the study at 18 months.

Efficacy Outcomes in DM

- Continued improvement in inflammatory skin involvement was observed in DM subjects using a composite outcome, the Cutaneous Dermatomyositis Activity and Severity Index (CDASI) activity score. The CDASI activity score improved from study start by a mean of -15.4 points at 6 months to -17.6 points at 12 months in the OLE. An improvement of -4 to -5 points in CDASI activity score is considered medically important, and 84% of subjects had improvement in CDASI activity score exceeding -10 points at 12 months in the OLE.
- Continued improvement during the OLE in patient-reported global assessments of skin activity, skin symptoms, itch and hair loss all supported improvement in inflammatory skin disease in these DM subjects.
- Continued improvement from study start and 6-month OLE data was seen in overall

disease as assessed with patient- and physician-reported global disease activity, physician assessment of extramuscular disease activity, and patient-reported pain. All subjects who entered the OLE completed 12 months of dosing.

Lenabasum has been granted Orphan Drug Designations for the treatment of [SSc](#) and [DM](#) and [Fast Track designation](#) for the treatment of SSc from the FDA and Orphan Designations for the treatment of [SSc](#) and [DM](#) from the EMA. Efficacy and safety of lenabasum in SSc is currently being evaluated in the international multicenter Phase 3 RESOLVE-1 study. Corbus plans to start a 1-year, double-blind, randomized, placebo-controlled Phase 3 study testing efficacy and safety of lenabasum in approximately 150 adults with DM by the end of 2018.

For more information about clinical trials of lenabasum in SSc and DM, please visit ClinicalTrials.gov and reference identifier NCT02465437 (Phase 2 SSc), NCT03398837 (Phase 3 SSc) or NCT02466243 (Phase 2 DM).

ACR Presentations

The abstract #1715, “*Safety and Efficacy of Lenabasum in an Open-Label Extension of a Phase 2 Study in Diffuse Cutaneous Systemic Sclerosis Subjects*,” will be presented today, Monday, October 22, 2018, in the *Systemic Sclerosis and Related Disorders – Clinical Poster II* Session, by Robert Spiera, M.D., Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery, Weill Cornell Medical College in New York City and Principal Investigator of the Phase 2 and Phase 3 trials in SSc. To access the poster, click [here](#).

The abstract #2284, “*Safety and Efficacy of Lenabasum in Refractory Skin-Predominant Dermatomyositis Subjects Treated on an Open-Label Extension of Trial JBT101-DM-001*,” will be presented on Tuesday, October 23, 2018 as part of the *Muscle Biology, Myositis and Myopathies Poster III: Treatment and Classification Criteria* Session, by Victoria Werth, M.D., Professor of Dermatology and Medicine at the University of Pennsylvania School of Medicine and Principal Investigator of Corbus’ Phase 2 study in Dermatomyositis. To access the poster, click [here](#). The double-blinded, placebo-controlled portion of the DM Phase 2 study was funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania Perelman School of Medicine.

The oral presentation, “*Lenabasum, a Cannabinoid Type 2 Receptor Agonist, Reduces T-Cell Population and Downregulates Type 1 and 2 Interferon Activities in Lesional Dermatomyositis Skin*,” will be presented on Wednesday, October 24, 2018 as part of the *Muscle Biology, Myositis & Myopathies II: Clinical & Misc Topics (2976–2981)* Session, by Dr. Werth. The double-blinded, placebo-controlled portion of the DM Phase 2 study was funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania Perelman School of Medicine. The slides from this oral presentation will be available on Corbus’ website following Dr. Werth’s presentation.

About Systemic Sclerosis

Systemic sclerosis (SSc), a form of scleroderma, is a chronic, rare systemic autoimmune

disease affecting approximately 200,000 people in the US, 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 (scarring) and small blood vessel damage in the skin and multiple other organs in the body. It is unknown why the body's immune system becomes and stays activated, damaging the body's own tissue in people with SSc.

Patients with SSc have signs and symptoms related to fibrosis in the skin and involvement of multiple other organs. The signs and symptoms of SSc vary depending upon which organs are affected and how badly they are affected. One type of SSc, diffuse cutaneous systemic sclerosis (dcSSc), has more widespread skin fibrosis, which may develop quickly and affect the face, arms, legs, chest and abdomen. The skin becomes thickened and may be swollen, feel tight, itchy, and painful, and undergo disfiguring pigment changes. Other symptoms of SSc can include: tiredness and weight loss from systemic inflammation; shortness of breath, limitation of daily activities, or heart failure from cardiopulmonary involvement; pain and restricted joint motion from joint and tendon involvement; heartburn, trouble swallowing food, bloating, diarrhea, constipation, and malnutrition from gastrointestinal system involvement; high blood pressure and renal failure from kidney involvement; and pain and limitation using the hands because of Raynaud's phenomenon or digital tip ulcers from small blood vessel involvement. Unfortunately, people with SSc have the high mortality rates when they have severe involvement of major organs.

Drugs that suppress the immune system are used to control SSc disease activity overall or in major organs. These drugs can include prednisone, methotrexate, mycophenolate, cyclophosphamide, and rituximab. These immunosuppressive treatments may be associated with significant side effects, such as serious infections, or may not be well tolerated. There are no treatments specifically approved for treatment of SSc by the FDA.

About Dermatomyositis

Dermatomyositis (DM), a form of idiopathic inflammatory myositis, is a chronic, rare systemic autoimmune disease affecting approximately 80,000 people in the US, EU and Japan. The disease is typically diagnosed in adults between 50 and 60 years old, although it can occur in children, and females are more commonly affected than males. Dermatomyositis is characterized by chronic inflammation, scarring or loss of cells in multiple organs, and damage to blood vessels. As with SSc, it is unknown why the body's immune system becomes and stays activated, damaging the skin, muscles, and other organs in people with DM.

People with DM have inflammatory skin rashes with or without muscle weakness and involvement of multiple other organs. The symptoms of DM vary depending on the organs involved and the severity of the involvement. Typically, reddish or purple inflammatory skin rashes appear on the face, chest, and hands. The rashes can be painful, intensely itchy, light-sensitive, and the skin can even ulcerate. The skin rashes generally precede, accompany, or follow progressive muscle weakness, although DM can occur without clinically apparent muscle involvement. Some people with DM need devices to help with arising or walking because of muscle atrophy and severe weakness. Deposits of calcium in the skin and muscles can be painful or ulcerate. Other symptoms of DM can include: tiredness and weight loss from systemic inflammation; shortness of breath and limitation of daily activities from cardiopulmonary involvement; pain from joint and tendon inflammation;

heartburn and trouble swallowing food from involvement of the esophagus; and pain in the hands because of Raynaud's phenomenon from small blood vessel involvement. Malignancy is more common in DM. Overall mortality rate in DM estimated to be about 30% at 5 years.

Immunosuppressive or immunomodulating drugs are typically prescribed to control DM disease activity overall or in major organs. Drugs that are used include high dose prednisone, methotrexate, mycophenolate, cyclophosphamide, azathioprine, rituximab, intravenous immunoglobulin, and anti-malarial drugs. These treatments may be associated with significant side effects, such as serious infections, or may not be well-tolerated. FDA-approved treatments for DM include systemic corticosteroids and adrenocorticotrophic hormone analogue.

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 induces the production of Specialized Pro-resolving lipid Mediators ("SPMs") that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Lenabasum also has 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 show lenabasum reduces expression of genes and proteins involved in inflammation and fibrosis. Lenabasum demonstrates 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 industry-leading 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. CRB-4001 is scheduled to enter a Phase 1 study in 2019 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.

Source: Corbus Pharmaceuticals Holdings, Inc.

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