November 9, 2020

Corbus Pharmaceuticals Presents Additional Data from RESOLVE-1 Study in Systemic Sclerosis

- Topline data remain as previously reported
- Post-hoc analyses showed lenabasum treatment was associated with a benefit in lung function (forced vital capacity) in subjects on established background immunosuppressant therapies (greater than 2 years)
- Focusing on forced vital capacity in patients on established immunosuppressant therapies could address a key unmet need and represents a potential commercial opportunity
- Systemic sclerosis is a rare, life-threatening autoimmune disease affecting up to 75K Americans

Norwood, MA, Nov. 09, 2020 (GLOBE NEWSWIRE) -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical-stage drug development company pioneering transformative medicines that target the endocannabinoid system, today presented additional data from the RESOLVE-1 Phase 3 study of lenabasum for the treatment of systemic sclerosis.

"We are encouraged by the post-hoc analyses pointing to lenabasum's therapeutic potential to reduce decline in lung function in people with systemic sclerosis who have been on longer-term immunosuppressant drug therapy," said Yuval Cohen, Ph.D., Chief Executive Officer of Corbus. "We believe these findings offer a rationale for additional clinical development of lenabasum, a non-immunosuppressive agent, that could address lung function decline in systemic sclerosis patients."

Summary of findings:

Modified intent-to-treat population (n = 363):

- Stable doses of background immunosuppressant therapies were allowed in both lenabasum and placebo arms, reflecting current clinical practice.
- 84% of RESOLVE-1 subjects were on background immunosuppressant therapies.
- As previously reported, median American College of Rheumatology Combined Response Index for Systemic Sclerosis (ACR CRISS) scores at Week 52 were 0.888 versus 0.887, for lenabasum 20 mg twice daily (n = 120) versus placebo (n = 123).

Placebo group (n = 123):

- Unprecedented improvement was seen in the placebo group in subjects who were concurrently receiving stable doses of background immunosuppressant therapies, especially subjects in their first two years on these therapies.
- Subjects treated with background mycophenolate had the greatest improvement over the one-year RESOLVE-1 study.

Post-hoc analyses of lenabasum 20 mg twice daily group compared to placebo group:

- In subjects receiving established background immunosuppressant therapies (> 2 years duration at baseline), lenabasum treatment (n = 38) versus placebo (n = 26) was associated with reduced decline in forced vital capacity (FVC) at one year, measured in milliliters (-21 mL versus -170 mL, nominal P = 0.048) or percent predicted (-0.4% versus -4.6%, nominal P = 0.039).
- Data from these subjects were also categorized as follows: FVC % decline (worsening by more than -5%), stable FVC % (values within 5% of baseline value) and improved FVC % (improvement more than 5%). Lenabasum 20 mg twice daily was associated with a lower likelihood of a decline (19% lenabasum versus 50% placebo), greater likelihood to have stable FVC % predicted (64% lenabasum versus 35% placebo), and similar likelihood in improvement (17% lenabasum versus 15% placebo, nominal P = 0.035).
- In a subset of these subjects with diagnosed interstitial/restrictive lung disease (ILD), lenabasum 20 mg twice daily was associated with numerically reduced decline in FVC at one year (-14 mL versus -121 mL and -0.3% versus -3.5%), lenabasum (n = 32) versus placebo (n = 20). ILD was identified by fibrosis on chest x-ray or computerized tomography of the lungs or baseline FVC < 80% predicted.

Safety findings:

- Lenabasum was safely administered and well tolerated in this study, with no new safety findings. Dizziness (18.3% lenabasum versus 4.9% placebo) and dry mouth (5.0% lenabasum versus 1.6% placebo) were among adverse events that occurred in ≥ 3% more subjects in the lenabasum 20 mg twice daily group versus the placebo group. No evidence of lenabasum-associated immunosuppression was seen.

The Company is continuing to analyze the data and will consider the potential for an additional study based on results of these analyses. Focusing on FVC in patients on established immunosuppressant therapies could address a key unmet need, and we believe represent a potential commercial opportunity.

Lenabasum has been granted Orphan Drug designation and Fast Track designation for the treatment of systemic sclerosis from the U.S. Food and Drug Administration (“FDA”).

Study design:

RESOLVE-1 was a Phase 3 study evaluating the efficacy and safety of lenabasum in 365 people with diffuse cutaneous systemic sclerosis on background drug therapy in North America, Europe, Asia, Israel, and Australia. This was a double-blind, randomized, placebo-controlled study, with dosing of lenabasum at 20 mg twice daily, lenabasum at 5 mg twice daily, or placebo twice daily for 52 weeks. The primary efficacy endpoint was the median ACR CRISS scores at Week 52. For more information on RESOLVE-1, please visit

ClinicalTrials.gov and reference Identifier: NCT03398837.

About Lenabasum

Lenabasum is a novel, oral, small molecule designed to provide an alternative to immunosuppressive treatments for inflammatory or fibrotic diseases. Lenabasum binds to and activates the cannabinoid receptor type 2 (CB2), which is preferentially expressed on activated immune cells, to resolve inflammation and limit fibrosis. Activity of lenabasum against inflammation and fibrosis has been demonstrated in animal and human models of disease. In clinical testing to date, lenabasum has an acceptable safety profile without evidence of immunosuppression, has not been associated with laboratory test abnormalities, and has been well-tolerated.

About Systemic Sclerosis

Systemic sclerosis is a form of the rare disease scleroderma in which internal organ involvement occurs. Systemic sclerosis is a chronic, debilitating autoimmune disease that affects approximately 200,000 people in the North America, EU and Japan.[1] It is considered one of the most life-threatening rheumatic diseases.[2] Disease pathology is characterized by inflammation and fibrosis (scarring of tissue) which can damage the skin, joints, tendons, gastrointestinal tract, lungs, heart, kidneys, and small blood vessels throughout the body.[3] There is no cure for systemic sclerosis, and current treatments address the clinical manifestations of the disease.[4]

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a clinical-stage company focused on the development and commercialization of novel medicines designed to target the endocannabinoid system. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist designed to provide an alternative to immunosuppressive medications in the treatment of chronic inflammatory and fibrotic diseases. Lenabasum is currently being evaluated in dermatomyositis and systemic lupus erythematosus. Corbus is also developing a pipeline of other preclinical drug candidates from its endocannabinoid system platform.

Lenabasum is not approved for the treatment of any indication. For more information on Corbus' clinical programs, please visit here.

For more information, visit http://www.corbuspharma.com/, and connect with us 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 restructuring, trial results, 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, including the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on our operations, clinical development plans and timelines, 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 Analysis

2. Elhai M, Meune C, Avouac J, Kahan A, Allanore Y. Trends in mortality in patients with systemic sclerosis over 40 years: a systematic review and meta-analysis of cohort studies. Rheumatology 2012;51(6):1017e26

3. Sierra-Sepulveda A, Esquinca-Gonzalez A, Benavides-Suarez SA, Sordo-Lima DE, Caballero-Islas AE, Cabral-Castaneda AR, et al. Systemic Sclerosis Pathogenesis and Emerging Therapies, beyond the Fibroblast. Biomed Res Int. 2019;2019:4569826

4. Scleroderma. National Institute of Arthritis and Musculoskeletal and Skin Diseases, U.S. Department of Health and Human Services, 5 November 2020, www.niams.nih.gov/health-topics/scleroderma/advanced#tab-risk.

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Source: Corbus Pharmaceuticals Holdings, Inc.