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Corbus Pharmaceuticals Reports Positive Topline Data Demonstrating Anabasum Reduces Acute Pulmonary Exacerbations and Multiple Inflammatory Biomarkers in Phase 2 Study in Patients with Cystic Fibrosis

Anabasum achieves primary study objective of acceptable safety and tolerability; Management to host conference call and webcast today at 8:00 a.m. EDT

NORWORD, MA -- (Marketwired) -- 03/30/17 -- [Corbus Pharmaceuticals Holdings, Inc.](#) (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, today announced positive topline data from its Phase 2 study evaluating multiple doses of [anabasum](#) (fka JBT-101 or Resunab) compared to placebo for the treatment of patients with cystic fibrosis ("CF"). The 16-week study dosed 85 adult CF patients with baseline forced expiratory volume in 1 second (FEV1) percent predicted $\geq 40\%$, who were enrolled without regard to their specific CFTR mutation or infecting pathogens and continued with all baseline treatment regimens.

Anabasum successfully achieved the primary objective of the study by demonstrating an acceptable safety and tolerability profile at all doses with no serious or severe adverse events related to the study drug.

Cystic Fibrosis Foundation Therapeutics, Inc. ("CFFT"), the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation, supported the Phase 2 study.

Anabasum cohorts showed a dose-dependent reduction in a number of acute pulmonary exacerbations defined as those requiring intravenous (IV) antibiotics compared to placebo. Patients in the highest dose cohort of anabasum (20 mg orally, twice per day) had a 75% reduction in the annualized rate of pulmonary exacerbations requiring IV antibiotics compared to placebo cohort.

Additionally, anabasum caused a consistent reduction in multiple inflammatory cell types in sputum, including total leukocytes, neutrophils, eosinophils, and macrophages. Inflammatory mediators, including interleukin-8, neutrophil elastase, and immunoglobulin G, were also

reduced in sputum by anabasum in a dose-dependent manner. These patient data provide evidence of biological activity of anabasum in resolving ongoing innate immune responses in lungs of CF patients and support the observed reduction in pulmonary exacerbations.

Serum concentrations of orally-administered anabasum in CF patients were similar to those previously observed in healthy volunteers. FEV1 remained stable throughout the duration of the study in all treatment cohorts.

"We are delighted that in this first-in-CF patient study, anabasum demonstrated an acceptable safety profile and potential clinical benefit in reducing acute pulmonary exacerbations in CF patients and that these findings are supported by biomarker data consistently showing reduction of inflammation in the lungs," stated [Yuval Cohen, PhD, CEO of Corbus](#). "These positive results coincide with our third anniversary as a company and come on the heels of positive data from our Phase 2 study in systemic sclerosis. We are very grateful to all the patients, investigators and clinical staff who participated in this study and to Cystic Fibrosis Foundation Therapeutics for their support."

"The reduction in acute pulmonary exacerbations along with reductions in inflammatory cells and inflammatory mediators in sputum demonstrate the potential for anabasum as a new inflammation-targeting therapeutic in cystic fibrosis that can broadly target patients without regard to their specific CFTR mutations. The outcomes of this 16-week study indicate that anabasum has the potential to address the important unmet need for treatments that target inflammation in CF," commented James Chmiel, M.D., M.P.H., Professor of Pediatrics, Case Western Reserve University, Associate Director of the LeRoy W. Matthews Cystic Fibrosis Center at University Hospitals Rainbow Babies and Children's Hospital in Cleveland, and Principle Investigator of Corbus' Phase 2 cystic fibrosis clinical study.

Study Design and Results

This was an international, multi-center, double-blinded, randomized, placebo-controlled Phase 2 study supported in part by a [\\$5 million Development Award from Cystic Fibrosis Foundation Therapeutics, Inc.](#) The primary objective of the study was to test safety and tolerability of anabasum in adults with CF who had FEV1 \geq 40 percent predicted and remained on background CF medications, including prophylactic antibiotics. Patients were enrolled without regard to their CFTR mutation, infecting pathogen, or baseline treatment. Acute pulmonary exacerbations requiring IV antibiotic treatment were captured as an event of special interest during the study. Secondary objectives included measurement of plasma concentrations and metabolites of anabasum and change from baseline in FEV1 percent predicted and Cystic Fibrosis Questionnaire-Revised Respiratory Symptom score. Additional outcomes included change from baseline in sputum and blood biomarkers of inflammation.

Eighty-five patients on stable standard-of-care medications were dosed with anabasum or placebo at 21 sites in the U.S. and Europe and treated for 84 days, with a follow-up period of 28 days off treatment. During the first part of the study (Weeks 1-4) patients were randomized to placebo (n = 35), 1 mg/day anabasum (n = 26) or 5 mg/day anabasum (n = 24). During the second part of the study (Weeks 5-12), anabasum patients were randomly assigned to anabasum 20 mg once per day (n = 31) or anabasum 20 mg twice per day (n = 30) with 11 patients from the placebo cohort randomly assigned to the 2 anabasum cohorts. Twenty-four patients continued to receive placebo in Weeks 5-12.

After dosing, 10 patients discontinued early from the study; 3 patients withdrew consent, 5 withdrew due to adverse events (2 on placebo, 3 on anabasum), 1 subject was lost to follow-up and 2 patients withdrew for treatment-unrelated reasons. Baseline characteristics were similar between anabasum and placebo cohorts.

Safety

During Weeks 1-4, treatment-emergent adverse events (TEAEs) occurred in 14 (54%) of patients in the anabasum 1 mg cohort, 13 (54%) of the anabasum 5 mg cohort and 15 (43%) of the placebo cohort. During Weeks 5-12, TEAEs occurred in 21 (68%) patients in the anabasum 20 mg once per day cohort, 19 (63%) of the anabasum 20 mg twice per day cohort and 14 (58%) of the placebo cohort. Six serious adverse events (SAEs) occurred the anabasum-treated patients and 6 SAEs occurred in placebo-treated patients. Three severe TEAEs occurred in the anabasum-treated patients and 4 in placebo-treated patients. None of the serious or severe TEAEs were assessed by site investigators to be related to study drug. The most common drug-related adverse event that occurred in more than 2 individuals was mild dry mouth observed in 8 (13%) of anabasum patients and no placebo patients. As expected, the respiratory system was the most common source of TEAEs overall.

C_{max} values for anabasum were similar to those previously measured in healthy human volunteers after similar doses of anabasum.

Acute Pulmonary Exacerbations

Treatment with anabasum yielded a dose-dependent reduction in acute pulmonary exacerbations. The highest dose of anabasum (20 mg twice per day) was associated with a 75% reduction in the annualized rate of pulmonary exacerbations requiring treatment with IV antibiotics, compared to placebo. Similar levels of reduction were also observed in acute pulmonary exacerbations defined by new or worsening respiratory symptoms requiring treatment with any antibiotic.

Inflammatory Cells and Biomarkers

Patients treated with anabasum 20 mg twice a day showed a consistent reduction in multiple inflammatory cell types in their sputum at the end of active treatment compared to placebo, including total leukocytes, neutrophils, eosinophils, lymphocytes and macrophages. They also had a consistent reduction in inflammatory mediators in their sputum including interleukin-8, neutrophil elastase and immunoglobulin G.

Next steps

[Barbara White, MD, Chief Medical Officer of Corbus](#) stated, "We are delighted that anabasum demonstrated a safety profile that was well tolerated by the CF patients in this study, especially given the challenges in safely targeting inflammation in CF. In a study of just 12-weeks of active dosing, we are especially encouraged by the consistency in data that couple clinical benefit in pulmonary exacerbations with improvement in the inflammatory response in the lungs. We believe these findings reflect the underlying mechanism of action of anabasum in activating resolution of innate immune responses without immunosuppression."

Corbus will engage in further evaluation of the data and design of the next clinical trial in partnership with CF experts, the Cystic Fibrosis Foundation Therapeutics, Inc., Cystic Fibrosis Therapeutic Development Network and European Cystic Fibrosis Society Clinical Trials Network. Thereafter, Corbus will enter into discussions with the relevant regulatory agencies.

Anabasum was granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of CF by the FDA in 2015 and Orphan Drug Status from the European Medicines Agency (EMA) in 2016.

For more information on the Phase 2 study with anabasum for the treatment of CF, please visit [ClinicalTrials.gov](#) and reference Identifier NCT02465450.

Conference Call and Webcast Information

Corbus management will host a conference call for investors, analysts and other interested parties today, March 30, 2017 at 8:00 am EDT to discuss the topline data from the Phase 2 Study evaluating anabasum for the treatment of CF.

The conference call and live webcast will be accompanied by presentation slides. To participate in the call, please dial (877) 407-3978 (domestic) or (412) 902-0039 (international). The live webcast and accompanying slides will be accessible on the [Events](#) page of the [Investors](#) section of Corbus website, www.corbuspharma.com, and will be archived for 60 days.

About Cystic Fibrosis

Cystic Fibrosis ("CF") is a chronic, life-threatening, genetic disease caused by inheriting two dysfunctional CFTR genes that normally regulate salt and water movement across cells in the respiratory and digestive systems. CF affects approximately 30,000 patients in the U.S and 75,000 patients worldwide. People with CF have thick, sticky mucus that clogs their airways, with recurrent bacterial infections and chronic inflammation in their lungs. In the gastrointestinal tract, they also have mucus accumulation, bacterial overgrowth, and inflammation. The dysfunctional CFTR genes cause an exaggerated inflammatory response that compounds the damage from a coexisting infection in the lungs and gut. CF results in destruction of lung tissue, lung fibrosis, pancreatic insufficiency, CF-related diabetes, malabsorption, malnutrition, growth retardation, and liver disease, including cirrhosis. The harmful inflammation and accompanying fibrosis in CF damages multiple organs, impairs organ function, reduces health-related quality of life, and can lead to death.

About Anabasum

Anabasum is a novel synthetic oral endocannabinoid-mimetic drug that preferentially binds to the CB2 receptor expressed on activated immune cells and fibroblasts. CB2 activation triggers endogenous pathways that resolve inflammation and halt fibrosis. Preclinical and Phase 1 studies have shown anabasum to have a favorable safety, tolerability and pharmacokinetic profile. It has also demonstrated promising potency in preclinical models of inflammation and fibrosis. Anabasum is designed to trigger the production of "Specialized Pro-resolving Lipid Mediators" that activate an endogenous cascade responsible for the resolution of inflammation and fibrosis, while reducing production of multiple inflammatory

mediators. Anabasum has direct effects on fibroblasts to halt tissue scarring. In effect, anabasum triggers endogenous pathways to turn "off" chronic inflammation and fibrotic processes, without causing immunosuppression.

About Corbus

Corbus Pharmaceuticals Holdings, Inc. is a clinical stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Our lead product candidate, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation, and fibrotic processes. Anabasum is currently in Phase 2 clinical studies for the treatment of cystic fibrosis, diffuse cutaneous systemic sclerosis and skin-predominant dermatomyositis, with a fourth Phase 2 trial in systemic lupus erythematosus planned to commence during the first half of 2017.

For more information, please visit www.CorbusPharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Google+](#) 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 trials, 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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