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Corbus Pharmaceuticals Reports Positive Topline Results from Phase 2 Study in Rare Autoimmune Disease Dermatomyositis

NORWOOD, MA -- (Marketwired) -- 10/19/17 --

- Data selected for late-breaking presentation at ACR on November 7, 2017
- Anabasum improved CDASI activity score by 9.3 points vs 3.7 for placebo at end of study ($p = 0.04$)
- First potential treatment for skin-predominant dermatomyositis to show clinical benefit in a double-blind, randomized, placebo-controlled trial
- Dermatomyositis is a rare disease which affects up to 70,000 people in the US and has a 10-year survival rate of 57%

[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 results from its 16-week Phase 2 study of safety and efficacy of [anabasum](#) in [dermatomyositis](#) ("DM"). The mean improvement (reduction) in the primary efficacy outcome, the Cutaneous Dermatomyositis Disease Area and Severity Index ("CDASI") activity score, a validated outcome measure of skin disease severity, was 9.3 points for anabasum treatment at the end of the study versus a reduction of 3.7 points for placebo treatment ($p = 0.04$). Anabasum also outperformed placebo in multiple secondary efficacy outcomes studied. Anabasum was well tolerated with no severe or serious side effects associated with the drug. No subjects dropped out.

Study Design

The single center, double-blind, randomized, placebo-controlled trial enrolled 22 adult subjects in a 1 to 1 ratio of anabasum to placebo cohorts. At baseline, subjects in each cohort had a mean CDASI activity score in the severe range and skin symptoms in the extremely severe range despite background treatment with immunosuppressive drugs in 19 of the 22 subjects. Demographic parameters, CDASI activity scores, patient-reported outcomes, and use of immunosuppressive drugs at baseline were similar for anabasum and placebo cohorts. Subjects received anabasum 20 mg QD through week 4, then anabasum 20 mg BID through week 12 with safety and efficacy follow-up thereafter through week 16.

All subjects remained on their background standard-of-care therapy throughout the study.

Primary Efficacy Endpoint

Improvement in CDASI activity scores in the anabasum cohort were ≥ 7.5 points and consistently superior to improvement in the placebo cohort from week 6 to end of study. The mean improvement (reduction) in CDASI activity score for the anabasum cohort (20 mg QD followed by 20 mg BID) from day 1 to end of study was 9.3 points versus 3.7 points for the placebo cohort ($p = 0.04$, 2-sided MMRM). The greater degree of improvement versus placebo in CDASI activity score occurred during dosing with anabasum 20 mg BID (treatment effect 6.3 points at end of study, $p = 0.02$, 2-sided MMRM). Improvement in CDASI activity score ≥ 4 points has been correlated with improvement in patient-reported quality of life outcomes, pain and physician global assessment.

Secondary Efficacy Endpoints and Safety Outcomes

Improvements across multiple secondary efficacy outcomes were seen in the anabasum cohort versus the placebo cohort, including statistically significant improvement in CDASI Damage Index ($p = 0.04$) and patient-reported symptoms and functioning. Anabasum was well tolerated and demonstrated a favorable safety profile with no serious or severe side effects related to the study drug and no study discontinuations.

Dr. Victoria Werth, MD, Chief, Dermatology, Philadelphia V.A. Hospital, Professor of Dermatology at the Hospital of the University of Pennsylvania and the Veteran's Administration Medical Center, Professor of Medicine, University of Pennsylvania and Principal Investigator in the Phase 2 study, stated, "I have extensive experience treating patients with DM and we currently have little to offer patients with moderate to severe disease activity except immunosuppressive therapies with often limited efficacy and significant side effects. My gratitude goes to the NIH for funding this first double-blind, randomized, placebo-controlled trial conducted in skin-predominant DM. The results signal a clear clinical benefit associated with anabasum with no evidence of immunosuppression. These positive data are even more striking given that the study was done in patients with high disease activity who remained on standard background immunosuppressive therapies during the study. Anabasum had minimal side effects and all patients completed the study, with nearly all of them volunteering for a long-term open label extension trial, which speaks to the excellent safety profile of anabasum and the need for effective treatments for DM."

[Barbara White, MD, Chief Medical Officer of Corbus](#) commented, "These results in this first-in-patient DM study in 22 subjects are exciting and demonstrate medically and statistically significant improvement in the primary endpoint in skin disease. Improvements in multiple secondary patient-reported outcomes, including a number that achieved statistical significance, reinforce the signal of activity of anabasum in DM. These data are consistent with our previously reported positive results from the completed Phase 2 systemic sclerosis trial -- these two systemic autoimmune diseases share certain aspects of disease pathogenesis, signs and symptoms of disease, and even significant mortality. We look forward to discussion with regulatory authorities regarding the clinical development path forward."

"These trial results mark the third time anabasum has demonstrated a clear signal of clinical benefit with a favorable safety profile in a rare, inflammatory disease, having done so

recently in both systemic sclerosis and cystic fibrosis," stated [Yuval Cohen, PhD, CEO of Corbus](#). "We view these data as a strong validation of the unique mechanism of action of anabasum as the potential first non-immunosuppressive pro-resolving drug to target inflammation and fibrosis. Our focus now turns to successfully executing a clinical development plan aimed at bringing anabasum to the market as expeditiously as possible."

The dermatomyositis trial 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.

Data Selected for Late Breaking Presentation at ACR

Detailed results of safety and primary and secondary efficacy assessments have been selected for a late-breaking poster presentation entitled "A Phase 2 Study of Safety and Efficacy of Anabasum (JBT-101), a Cannabinoid Receptor Type 2 Agonist, in Refractory Skin-Predominant Dermatomyositis" on November 7, 2017 at 9:00 -11:00 AM PDT at the American College of Rheumatology ("ACR") Annual Meeting being held November 3-8 in San Diego, CA. Demographics and baseline characteristics of subjects will be presented in a second poster presentation (abstract 2156) entitled: "Comparison of Patients with Dermatomyositis in a Specialty Clinic Versus Clinical Trial with Anabasum (JBT-101), a Cannabinoid Receptor Type 2 Agonist."

About Dermatomyositis

Dermatomyositis is a rare and serious systemic autoimmune condition characterized by skin and muscle involvement. Like other autoimmune diseases, it affects more women than men and morbidity is more severe in black, Asian and Native American populations. The disease is characterized by distinct skin lesions that can be accompanied by erosions, photosensitivity, itch, ulcers, calcinosis and hair loss as well as other abnormalities. Muscle inflammation and atrophy is a characteristic of the disease and can manifest as weakness. Dermatomyositis affects as many as 70,000 people in the US. Mortality is high with 5-year survival of 70% and 10-year survival of 57%. Standard of care includes antimalarial drugs and potent immunosuppressive agents, which often lead to significant adverse effects.

About Anabasum

Anabasum is a synthetic oral endocannabinoid-mimetic drug that preferentially binds to cannabinoid receptor type 2 (CB2) expressed on activated immune cells and fibroblasts. CB2 activation triggers physiologic pathways that resolve inflammation, speed bacterial clearance and halt fibrosis. Nonclinical and human clinical studies to date have shown anabasum has favorable safety, tolerability and pharmacokinetic profiles. It has also demonstrated promising potency in nonclinical 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 also is designed to have a direct effect on fibroblasts to halt tissue scarring. In effect, anabasum is believed to trigger endogenous pathways to turn "off" chronic inflammation and fibrotic processes without causing immunosuppression.

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 rare, chronic, and serious inflammatory and fibrotic diseases. The Company's lead product candidate, anabasum, is a novel synthetic oral endocannabinoid-mimetic drug designed to resolve chronic inflammation and fibrotic processes. Anabasum has generated positive data in Phase 2 studies in diffuse cutaneous systemic sclerosis, cystic fibrosis and dermatomyositis. Additionally, the Company is evaluating anabasum in open-label extension studies in systemic sclerosis and skin-predominant dermatomyositis. The Company expects to commence a Phase 2 study in systemic lupus erythematosus, a Phase 3 study in systemic sclerosis and a Phase 2b study in cystic fibrosis in the fourth quarter 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 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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