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# Corbus Pharmaceuticals Reports Significant Improvement in mRSS and Other Clinical Outcomes at 28-Weeks in Systemic Sclerosis Open-Label Extension of Phase 2 Study

NORWOOD, MA -- (Marketwired) -- 11/06/17 --

- *Systemic sclerosis is a rare autoimmune disease with no approved therapies, affecting 90,000 individuals in US and EU with a 10-year mortality rate of 35-50%*
- *Anabasum achieved reduction in mRSS of 8.4 points from start of study ( $p < 0.0001$ , 2-side paired t-test) exceeding clinically important improvement (-4.7 points)*
- *75% of subjects achieved degree of improvement in mRSS correlated with improved survival*
- *Clinical benefit supported by improvement in multiple secondary outcomes and a continued favorable safety profile*
- *Company on track to commence Phase 3 study Q4 2017*

[Corbus Pharmaceuticals Holdings, Inc.](#) (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, yesterday presented 6-month safety and efficacy data from the open-label extension ("OLE") dosing in its ongoing Phase 2 study of anabasum ("JBT101-SSc-001") in subjects with diffuse cutaneous [systemic sclerosis](#) ("SSc"). The results were presented at the [American College of Rheumatology \("ACR"\) Annual Meeting](#) in San Diego, CA in a poster entitled: "*Safety and Efficacy of Anabasum (JBT-101) in Diffuse Cutaneous Systemic Sclerosis (dcSSc) Subjects Treated in an Open-Label Extension of Trial JBT101-SSc-001.*" To access the poster click [here](#).

[Anabasum](#) demonstrated a significant and clinically meaningful reduction in mRSS reaching minus 8.4 ( $p < 0.0001$  2-paired t-test) and an ACR CRISS of 71% at 28 weeks OLE. These responses exceeded those seen in the 12-week double-blind placebo-controlled dosing and increased at each visit with 33% of subjects achieving low mRSS scores ( $\leq 10$  points) and 44% achieving a high ACR CRISS  $\geq 70\%$ .

[Barbara White, M.D., Chief Medical Officer of the Company](#) stated, "The consistency and magnitude of efficacy seen with longer dosing increases our confidence that anabasum could offer a meaningful benefit to patients with SSc. The speed and degree of improvement in multiple efficacy outcomes at this stage in the open-label extension of our Phase 2 study

exceeds that previously reported in other clinical trials or registries in SSc."

"Keeping in mind the caveats of an open-label extension study, this level of improvement in this relatively short interval is impressive in the context of data from previous clinical studies in SSc," commented Principal Investigator 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. "Particularly striking was the loss of the measured CRISS response, our primary outcome in the Phase 2 study, when patients were off medication prior to enrolling in open label extension, with that response again captured when they resumed anabasum. This improvement comes with very manageable safety risks, including no significant changes in laboratory safety test results. I look forward to leading the Phase 3 study."

"These safety and efficacy data are very encouraging and reinforce the positive findings in the double-blinded placebo-controlled part of the study," added [Yuval Cohen, Ph.D., Chief Executive Officer of Corbus](#). "Systemic sclerosis is a very challenging disease and no SSc-specific drugs have been approved by the FDA. Our focus now is to ensure the successful execution of our Phase 3 study, and we are on track to commence this before year end."

### ***Study Design***

Thirty-six subjects with diffuse cutaneous SSc received open-label dosing with anabasum at 20 mg twice per day following 16-weeks participation in the preceding double-blinded placebo-controlled part of the anabasum Phase 2 study. Anabasum treatment was in addition to standard-of-care treatments for SSc, including stable doses of concomitant immunosuppressive drugs in 92% of subjects.

### ***Efficacy Outcomes***

The modified Rodnan Skin Score (mRSS), the primary outcome for the upcoming Phase 3 study of anabasum in SSc, improved by a mean of -8.4 points ( $p < 0.0001$ ) from baseline at the start of the Phase 2 double blind placebo controlled portion of the study. The baseline mRSS at study start was 24 points. 75% of subjects achieved a degree of improvement in mRSS (reduction  $\geq 5$  points and  $> 25\%$  baseline) that has been associated with improved survival in SSc. A third of subjects reached a low mRSS  $\leq 10$  points.

The ACR Composite Response Index in diffuse cutaneous Systemic Sclerosis score (ACR CRISS) increased steadily with anabasum treatment and reached 71% (median) from study start with 44% of subjects achieving a score  $\geq 70\%$ . The magnitude of this change is more than double what has been observed in analyses of data from clinical studies with other therapeutics. Patient-reported disability, function, skin symptoms and global health all improved from study start and OLE start. Forced vital capacity (FVC) % predicted was stable during anabasum treatment (mean change 0.3% predicted from study start) in contrast to the natural history of a decline in FVC in the disease.

### ***Safety***

There were no severe or serious adverse events (AEs) and no clinically significant laboratory abnormalities related to the drug. Thirty (83%) subjects experienced adverse events (AEs) and only 3 (8%) subjects experienced AEs related to anabasum during open-label dosing. The AEs experienced by  $\geq 10\%$  of subjects were upper respiratory tract illness in 7 (19%)

subjects and urinary tract infection in 5 (14%) subjects.

Anabasum has been granted [Orphan Drug Designation](#) and [Fast Track](#) status for the treatment of systemic sclerosis from the FDA and [Orphan Designation](#) from the EMA.

### ***About Systemic Sclerosis***

Systemic sclerosis is a rare and serious systemic autoimmune rheumatic disease with an unclear etiology. Systemic sclerosis affects approximately 90,000 people in the United States and Europe, with disease onset typically in mid-life. About 80 percent of SSc patients are women. The disease process in systemic sclerosis includes activation of the immune system, with damage to small blood vessels and fibrosis of the skin on internal organs, including lungs, heart, kidneys, gastrointestinal tract and musculoskeletal system. Chronic disease burden, morbidity and mortality are significant. Ten-year mortality rates are high at about 35-50%. Cardiopulmonary disease is the major cause of death in SSc.

Immunosuppressive medications such as oral corticosteroids, mycophenolate, methotrexate and cyclophosphamide are used to treat patients with more severe signs and symptoms of disease. Currently, there are no FDA-approved treatments specifically indicated for the treatment of systemic sclerosis, other than pulmonary artery hypertension secondary to connective tissue diseases such as systemic sclerosis.

### ***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](http://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.

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