

# Corbus Pharmaceuticals to Present New Data from Systemic Sclerosis Phase 2 Study of Anabasum at the 15th International Workshop on Scleroderma Research

Skin histology data from Phase 2 study participants provides further evidence for on-target effects of anabasum on inflammation and fibrosis

NORWOOD, MA -- (Marketwired) -- 08/07/17 -- Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP) ("Corbus" or the "Company"), a clinical stage drug development company targeting rare, chronic, serious inflammatory and fibrotic diseases, announced today that recently analyzed skin biopsy histology data from its Phase 2 study of <a href="mailto:anabasum">anabasum</a> for the treatment of diffuse cutaneous systemic sclerosis will be presented at the <a href="mailto:15th International Workshop on Scleroderma Research">15th International Workshop on Scleroderma Research</a>. The four-day biennial research meeting, centered on translational medicine related to systemic sclerosis (SSc), is being held August 5-9, 2017 at the University of Pittsburgh in Pittsburgh, PA.

Barbara White, MD, Chief Medical Officer of the Company will present the data from the Phase 2 study of anabasum in diffuse cutaneous systemic sclerosis today, Monday, August 7, as part of the *New Therapeutic Approaches and Translational Observations* session. To view Dr. White's presentation, please click here.

Skin biopsies from 34 participants were obtained on Day 1 of the study as well as at the end of treatment at 12 weeks. Histology slides from the biopsies were read in matched pairs without knowledge of treatment assignment for change from baseline in inflammation and fibrosis. The results showed significant improvement in inflammation (p=0.008) and fibrosis (p=0.049) in patients that were treated with anabasum (n=21) versus patients treated with placebo (n=13).

Better histology outcomes in the skin biopsies correspond with greater improvement in the modified Rodnan Skin Score (mRSS), a standard measurement of skin improvement in systemic sclerosis and the primary endpoint in the Company's upcoming Phase 3 study with anabasum.

"The histology data from this study show a striking difference between anabasum and placebo," commented Robert Lafyatis, MD, Division of Rheumatology and Clinical

Immunology at the University of Pittsburgh, who analyzed the skin biopsies. "The impact of anabasum on both inflammation and fibrosis in just 12 weeks as compared to the natural history of the disease is something that has not been demonstrated before."

"These new data provide robust additional evidence for on-target effects of anabasum on inflammation and fibrosis in systemic sclerosis patients and are consistent with the previously reported changes in gene-transcript data in skin biopsies from the same patients," commented Dr. White.

In November 2016, the Company reported positive topline data from its Phase 2 study in systemic sclerosis. In addition to improving mRSS, the Company reported that anabasum outperformed placebo in the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS) and multiple individual core measures in the ACR CRISS. The Company plans to commence a Phase 3 study in systemic sclerosis in the fourth quarter of this year. Corbus also has an ongoing open-label extension to its Phase 2 study of anabasum for systemic sclerosis which was recently extended from 12 to 24 months' duration. Anabasum has received Orphan Drug Designation and Fast Track status by the FDA for the treatment of systemic sclerosis and Orphan Drug Designation by the EMA.

For more information on the 15<sup>th</sup> International Workshop on Scleroderma Research, please visit the conference website <u>here</u>.

### 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 human clinical 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 also is designed to have 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 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 demonstrated positive results in two Phase 2 studies, one in diffuse cutaneous systemic sclerosis and one in cystic fibrosis. Additionally, anabasum is being evaluated in a 12-month open-label extension study in systemic sclerosis, a Phase 2 study in skin-predominant dermatomyositis with a 12-month open-label extension, and soon in another Phase 2 study in systemic lupus erythematosus.

Corbus plans to commence a Phase 3 study) of anabasum for the treatment of systemic

sclerosis in the fourth quarter of 2017. The Company is also planning to initiate a larger and longer Phase 2b study of anabasum for the treatment of cystic fibrosis by the end of 2017.

For more information, please visit <u>www.CorbusPharma.com</u> and connect with the Company on <u>Twitter</u>, <u>LinkedIn</u>, <u>Google+</u> and <u>Facebook</u>.

# 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.

## **Investor Contact**

Jenene Thomas

Jenene Thomas Communications, LLC

Phone: +1 (908) 938-1475

Email: Email contact

Media Contact
David Connolly
JPA Health Communications

Phone: (617) 657-1301 Email: Email contact

Source: Corbus Pharmaceuticals Holdings, Inc.