



## Corbus Pharmaceuticals Updates Data from Lenabasum Open-Label Extension Studies in Systemic Sclerosis and Dermatomyositis at 2019 ACR Annual Meeting

- *Median ACR CRISS score remains 0.95 at 25 months in systemic sclerosis OLE*
- *Improvement in CDASI activity score reaches -20.9 points at 23 months in dermatomyositis OLE*
- *Favorable safety profile continues with no serious or severe AEs related to lenabasum reported in these studies to date*
- *Topline results from RESOLVE-1 Phase 3 study of lenabasum in systemic sclerosis expected summer 2020*

**Norwood, MA, Nov. 11, 2019 (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 announced continued favorable safety and efficacy outcomes in open-label extensions (OLE) of lenabasum Phase 2 studies in two rare and serious autoimmune diseases: systemic sclerosis (SSc) and dermatomyositis (DM). These data are being presented at the [American College of Rheumatology \("ACR"\) 2019 Annual Meeting](#) being held November 8-13, 2019 in Atlanta, Georgia.

"The persistently favorable safety profile and durable improvement in efficacy outcomes, with over 2 years of dosing in these OLEs, support our optimism that the Phase 3 SSc study will show positive data in summer 2020. We interpret the durable improvement in multiple efficacy outcomes as an indicator showing totality of benefit for these diseases. The high rate of subject retention in these OLEs speaks to the enthusiasm of both the patients and their physicians for lenabasum as a potential treatment for SSc and DM. We are deeply grateful to the patients, physicians and site staff participating in these studies," said Barbara White, M.D., Chief Medical Officer and Head of Research for the Company.

### **Efficacy and Safety Outcomes in Systemic Sclerosis OLE**

- 29/36 (81%) of subjects who enrolled in the OLE were still enrolled at Month 25.
- ACR CRISS score remained  $\geq 0.95$  from Month 12 through Month 25 in the OLE. An ACR CRISS score of  $\geq 0.60$  at 1 year has been reported to be medically important.
- mRSS improved  $> 9.2$  points during the same time. An improvement of -4 to -5 points

in mRSS at 12 months has been reported to be medically important.

- Patient and physician global assessments of health, skin symptoms, itch, and patient-reported disability and function showed either stabilization or continued improvement during the OLE from Month 12 through 25.
- Mean Forced Vital Capacity (FVC) % predicted declined -2.0% from study start through latest data cut in September 2019.
- No severe or serious adverse events (AE) or study discontinuations related to lenabasum to date in the OLE.
- 35 of 36 subjects (97%) had  $\geq 1$  AE during  $\geq 25$  months dosing the OLE, for a total of 294 AEs through September 25, 2019.

Efficacy and safety of lenabasum in SSc is currently being evaluated in the Company's global RESOLVE-1 Phase 3 study. Enrollment is complete, and the baseline characteristics of subjects are similar to those in the Phase 2 study: 2/3<sup>rd</sup> of the subjects with disease duration < 3 years and 1/3<sup>rd</sup> with disease duration 3-6 years; mean age 50 years; 76% female; 68% Caucasian; 49% with history of interstitial lung disease; 84% on any immunosuppressive drug; mean mRSS 22.5; mean HAQ-DI 1.1; and mean FVC percent predicted 80%. The Company expects topline data in summer 2020.

Lenabasum has been granted Orphan Drug designation and Fast Track designation for lenabasum for the treatment of SSc from the FDA and Orphan Designation for the treatment of SSc from the EMA. Lenabasum is not approved for the treatment of systemic sclerosis.

### **Efficacy and Safety Outcomes in Dermatomyositis OLE**

- 18/20 (90%) of subjects were still enrolled in the OLE at Month 23.
- The Cutaneous Dermatomyositis Activity and Severity Index (CDASI) activity score continued to improve with a mean change of -20.9 points from baseline at Month 23. An improvement of -4 to -5 points in CDASI activity score at 12 months has been reported to be medically important.
- Patient-reported outcomes, including disease activity, skin activity, itch, pain, and effect on skin on functioning, symptoms and emotions, continued to improve or showed stable improvement from Month 12 to Month 23.
- No severe or serious AEs or study discontinuations related to lenabasum to date in the OLE.
- 20/20 (100%) of subjects had  $\geq 1$  AE during  $\geq 23$  months dosing the OLE, for a total of 69 AEs through September 25, 2019.

Efficacy and safety of lenabasum in DM is currently being evaluated in the Company's international, multicenter DETERMINE Phase 3 study. Enrollment is ongoing, and topline data are expected in 2021. Lenabasum has been granted Orphan Drug Designation for the treatment of DM from the FDA and EMA. Lenabasum is not approved for the treatment of dermatomyositis.

### **ACR Oral Presentation and Poster Details:**

The abstract #865, *Safety and Efficacy of Lenabasum at 21 Months in an Open-Label Extension of a Phase 2 Study in Diffuse Cutaneous Systemic Sclerosis Subjects*, was presented on Sunday, November 10, 2019 in the Systemic Sclerosis & Related Disorder – Clinical I: Therapeutics & Outcomes (863–868) session by 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 and Principal Investigator of the Phase 2 study in systemic sclerosis. *To access the slides from this oral presentation, [click here](#).*

The abstract #720, *Baseline Subject Demographics and Disease Characteristics in a Phase 3 Study of Safety and Efficacy of Lenabasum in Diffuse Cutaneous Systemic Sclerosis*, was presented on Sunday, November 10, 2019 in the Systemic Sclerosis & Related Disorders – Clinical Poster I session by 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 and Principal Investigator of the Phase 2 study in systemic sclerosis. *To access the poster, [click here](#).*

The abstract #2843, *Safety and Efficacy of Lenabasum at Week 68 in an Open-Label Extension of a Phase 2 Study of Lenabasum in Refractory Skin-Predominant Dermatomyositis (DM) Subjects*, will be presented on Tuesday, November 12, 2019 in the Muscle Biology, Myositis & Myopathies II (2840–2845) session by Victoria Werth, M.D., Professor of Dermatology and Medicine at the University of Pennsylvania Perelman School of Medicine and Principal Investigator of Corbus' Phase 2 study in dermatomyositis. *The slides from this oral presentation will be available on Corbus' website in the [Scientific Conferences](#) section following Dr. Werth's presentation.*

## **About Lenabasum**

Lenabasum is a rationally designed, oral, small molecule that selectively binds as an agonist to the cannabinoid receptor type 2 (CB2) and has been designed to resolve inflammation, limit fibrosis and support tissue repair. CB2 is preferentially expressed on activated immune cells and on fibroblasts, muscle cells, and endothelial cells. In both animal and human studies conducted to date, lenabasum has induced the production of pro-resolving lipid mediators that activate endogenous pathways which resolve inflammation and speed bacterial clearance without immunosuppression. Data from animal models and human clinical studies suggest that lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. Lenabasum has demonstrated promising activity in animal models of skin and lung inflammation and fibrosis in systemic sclerosis (SSc). Lenabasum is also active in animal models of lung infection and inflammation in cystic fibrosis and joint inflammation and scarring in rheumatoid arthritis.

Lenabasum has demonstrated acceptable safety and tolerability profiles in clinical studies to date. Lenabasum treatment was associated with improvement in multiple physician-assessed and patient-reported efficacy outcomes in Phase 2 studies in patients with diffuse cutaneous SSc and patients with DM with active skin involvement but not currently active muscle involvement. Lenabasum treatment also was associated with a lower rate of and longer time to pulmonary exacerbations in a Phase 2 cystic fibrosis study. Additional clinical studies are being conducted to confirm these results and support applications for regulatory approval.

## **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 inflammatory and fibrotic diseases by leveraging its pipeline of rationally designed,

endocannabinoid system-targeting drug candidates. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist rationally designed to resolve chronic inflammation and fibrotic processes. Lenabasum is currently being evaluated in systemic sclerosis, cystic fibrosis, dermatomyositis and systemic lupus erythematosus.

Corbus is also developing a pipeline of drug candidates targeting the endocannabinoid system. The pipeline includes CRB-4001, a 2nd generation, selective cannabinoid receptor type 1 (CB1) inverse agonist designed to be peripherally restricted. Potential indications for CRB-4001 include nonalcoholic steatohepatitis (NASH), among others. Corbus expects data from a CRB-4001 Phase 1 safety study in 2020.

For more information, please visit [www.CorbusPharma.com](http://www.CorbusPharma.com) and connect with the Company on [Twitter](#), [LinkedIn](#), and [Facebook](#).

Lenabasum is not approved for the treatment of systemic sclerosis, dermatomyositis, cystic fibrosis or systemic lupus erythematosus. CRB-4001 is not approved for the treatment of NASH/NAFLD.

### **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.

### **Corbus Pharmaceuticals Contacts:**

Ted Jenkins, Senior Director, Investor Relations and Corporate Communications  
Phone: +1 (617) 415-7745  
Email: [ir@corbuspharma.com](mailto:ir@corbuspharma.com)

Lindsey Smith, Associate Director, Investor Relations and Corporate Communications  
Phone: +1 (617) 415-7749  
Email: [mediainfo@corbuspharma.com](mailto:mediainfo@corbuspharma.com)

Jenene Thomas  
Jenene Thomas Communications, LLC  
Phone: +1 (833) 475-8247  
Email: [crbp@jtcir.com](mailto:crbp@jtcir.com)



Source: Corbus Pharmaceuticals Holdings, Inc.