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# Corbus Pharmaceuticals Reports Last Subject Visit in DETERMINE Phase 3 Study of Lenabasum for Treatment of Dermatomyositis

- *Topline data on schedule for Q2 2021*
- *Dermatomyositis is a rare and life-threatening autoimmune disease characterized by skin and muscle inflammation, and affects ~80,000 people in North America, EU, and Japan*
- *There is a significant need for safer and more effective treatments in dermatomyositis because of limitations of current treatment options*

**Norwood, MA, March 30, 2021 (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 that the last subject completed the final visit in the double-blind, placebo-controlled part of the Company's Phase 3 **DETERMINE** study of lenabasum for the treatment of dermatomyositis. The open-label extension of the study is ongoing. Topline results from the study are on track to be reported in the second quarter of 2021.

The Phase 3 trial is an international, 176-subject study evaluating the safety and efficacy of lenabasum in adult dermatomyositis patients who are receiving standard treatments, including background immunosuppressive therapies. This study is the largest randomized, double-blind, placebo-controlled dermatomyositis study to date. Subjects were randomized 2:1:2 to either receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day.

The primary efficacy endpoint is the composite American College of Rheumatology/European League Against Rheumatism 2016 Total Improvement Score ("Total Improvement Score") at Week 28. Change from baseline will be provided for each component of the Total Improvement Score to support this composite endpoint. Definition of Improvement, Investigator Global Assessment scale of skin activity, and Cutaneous Dermatomyositis Activity and Severity Index activity score are among secondary efficacy endpoints.

Lenabasum was granted Orphan Drug Designation for the treatment of dermatomyositis from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

## **About Lenabasum**

Lenabasum is a novel, oral, small molecule designed to provide an alternative to immunosuppressive treatments for inflammatory or fibrotic diseases. Lenabasum binds to and activates the cannabinoid receptor type 2 (CB2), which is preferentially expressed on activated immune cells, to resolve inflammation and limit fibrosis. Data from animal models and human clinical studies suggest that lenabasum can reduce expression of genes and proteins involved in inflammation and fibrosis. In clinical testing to date, lenabasum has an acceptable safety and tolerability profiles without evidence of immunosuppression.

## **About Dermatomyositis**

Dermatomyositis (DM), a form of myositis, is a chronic, rare, inflammatory, clinically heterogeneous, life-threatening autoimmune disease affecting approximately 80,000 people in North America, EU and Japan.<sup>1</sup> The signs and symptoms of DM reflect multi-organ involvement, which includes distinctive skin rashes usually accompanied by proximal muscle weakness, and can also include pulmonary, cardiac, gastrointestinal, and joint involvement.<sup>2</sup> Patients with DM can have recurrent disease flares or chronic progressive disease activity, with increased mortality.<sup>3,4</sup> The current mainstay of treatments include FDA-approved systemic glucocorticoids, adrenocorticotropic hormone analogue and off-label use of glucocorticoid-sparing immunosuppressive agents.<sup>5,6</sup> There is significant unmet need for new treatments to achieve disease control in DM because of limited efficacy or toxicity of immunosuppressive agents or refractory disease.<sup>7,8</sup>

## **About Corbus**

Corbus Pharmaceuticals Holdings, Inc. is a clinical-stage company focused on the development and commercialization of novel medicines designed to target the endocannabinoid system. The Company's lead product candidate, lenabasum, is a novel, oral, selective cannabinoid receptor type 2 (CB2) agonist designed to provide an alternative to immunosuppressive medications in the treatment of chronic inflammatory and fibrotic diseases. Lenabasum is currently being evaluated in dermatomyositis and systemic lupus erythematosus. Corbus is also developing a pipeline of other preclinical drug candidates from its endocannabinoid system platform.

Lenabasum is not approved for the treatment of any indication. For more information on Corbus' clinical programs, please visit [here](#).

For more information, visit [www.corbuspharma.com](http://www.corbuspharma.com), and connect with us on [Twitter](#), [LinkedIn](#), 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 restructuring, trial results, 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, including the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on our operations, clinical development plans and timelines, 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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Source: Corbus Pharmaceuticals Holdings, Inc.