

Idera Pharmaceuticals Reports Results from Phase 2 Trial of IMO-8400 in Dermatomyositis

June 12, 2018 11:30 AM EDT

Clinical trial did not meet primary endpoint of statistically significant reduction of CDASI for IMO-8400 versus placebo

EXTON, Pa., June 12, 2018 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with rare cancers and rare diseases, today announced topline results from the Phase 2 clinical trial of IMO-8400 in adult patients with dermatomyositis.

The objective of the multi-center, global, Phase 2, randomized, double blind, placebo-controlled trial was to assess the efficacy, safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), disease-specific autoantibodies and immunogenicity of IMO-8400 in adult patients with dermatomyositis. The primary objective of the trial was to assess the change from baseline in the Cutaneous Dermatomyositis Disease Area and Severity Index ("CDASI") activity score, an outcome measure of skin disease severity, versus placebo.

30 eligible subjects were randomized to 1 of 3 treatment groups to receive once weekly subcutaneous injections of 0.6 or 1.8 mg/kg of IMO-8400 or placebo for up to 24 weeks. The mean CDASI activity score was in the severe range in all three cohorts despite background treatment with immunosuppressive drugs and/or systemic corticosteroid drugs in 17 of the 30 subjects.

The trial did not meet its primary endpoint of statistically significant change from baseline in the CDASI activity score versus placebo.

The company would like to recognize the efforts of the investigators from this trial and importantly the patients who entered this trial in the hope that IMO-8400 may have been an effective treatment for their disease.

About Idera Pharmaceuticals

Harnessing the approach of the earliest researchers in immunotherapy and the Company's vast experience in developing proprietary immunology platforms, Idera's lead development program is focused on priming the immune system to play a more powerful role in fighting cancer, ultimately increasing the number of people who can benefit from immunotherapy. Idera continues to invest in research and development, and is committed to working with investigators and partners who share the common goal of addressing the unmet needs of patients suffering from rare, life-threatening diseases. To learn more about Idera, visit www.iderapharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, clinical trials, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether the Company's cash resources will be sufficient to fund the Company's continuing operations and the further development of the Company's programs for the period anticipated; whether interim results from a clinical trial, such as the preliminary results reported in this release, will be predictive of the final results of the trial; whether results obtained in preclinical studies and clinical trials such as the results described in this release will be indicative of the results that will be generated in future clinical trials, including in clinical trials in different disease indications; whether products based on Idera's technology will advance into or through the clinical trial process when anticipated or at all or warrant submission for regulatory approval; whether such products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; whether the Company's collaborations will be successful, and such other important factors as are set forth under the caption "Risk factors" in the Company's Annual Report filed on Form 10-K for the period ended December 31, 2016. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

¹Prieto (2010).

Investor and Media Contact

Robert Doody Vice President, Investor Relations and Corporate Communications

Office: 617-679-5515 Mobile: 484-639-7235 rdoody@iderapharma.com



Source: Idera Pharmaceuticals, Inc.