



Arena Pharmaceuticals Announces First Subject Dosed in ADVISE Phase 2 Trial Evaluating Etrasimod in Atopic Dermatitis

October 28, 2019

- ADVISE clinical trial initiated and enrollment progressing
- Evaluating patients with the clinical diagnosis of moderate-to-severe atopic dermatitis
- Significant unmet need for an oral therapy in atopic dermatitis

SAN DIEGO, Oct. 28, 2019 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (Nasdaq: ARNA) today announced that the first subject has been dosed in the Phase 2 ADVISE trial evaluating etrasimod, an investigational next-generation, once-daily, oral, selective sphingosine 1-phosphate (S1P) receptor modulator, for the potential treatment of moderate-to-severe atopic dermatitis (AD). The trial will evaluate the efficacy and safety of two doses of etrasimod for 12-weeks in approximately 120 subjects in sites across the United States, Canada and Australia.

"I am pleased that Arena is currently enrolling patients in its Phase 2 ADVISE study, advancing an oral agent with a novel mechanism of action for the potential treatment of atopic dermatitis," said Jonathan I. Silverberg, MD, PhD, MPH, Associate Professor of Dermatology, Director of Clinical Research, and Director of Patch Testing, at the George Washington University School of Medicine and Health Sciences. "Moderate-to-severe atopic dermatitis remains a disease with significant unmet medical needs. Patients and their families experience great burden on their quality of life and overall health, with negative impacts on physical and emotional well-being, social functioning, and activities of daily living."

"The decision to move into dermatology, and specifically atopic dermatitis, is founded on scientific, preclinical and early clinical supporting evidence," stated Preston Klassen, MD, MHS, Executive Vice President, Head of Research and Development at Arena. "We are confident that etrasimod has the potential to be a first-in-class oral therapy in atopic dermatitis, and we look forward to seeing the Phase 2 data in the second half of 2020."

About ADVISE

ADVISE is a Phase 2 multicenter, randomized, double-blinded, placebo-controlled study (with an open-label extension) to assess the safety and efficacy of once-daily etrasimod in subjects with moderate-to-severe atopic dermatitis. The primary endpoint is percent change in Eczema Area and Severity Index (EASI) from baseline to week 12, followed by a 4-week follow-up observation period. The ADVISE trial will enroll approximately 120 subjects and will be conducted in study sites across the United States, Canada and Australia.

About Atopic Dermatitis

Atopic dermatitis (AD) is a serious, chronic immune-mediated disease in which symptoms vary, but often include severe dry skin, itching, patches, swollen skin and raised bumps which may leak fluid.

About Etrasimod

Etrasimod (APD334) is a next generation, once-daily, oral, highly selective sphingosine 1-phosphate (S1P) receptor modulator discovered by Arena, and designed for optimized pharmacology and engagement of S1P receptor 1, 4 and 5 which may lead to an improved efficacy and safety profile.

Etrasimod provides systemic and local effects on specific immune cell types and has the potential to treat multiple immune-mediated inflammatory diseases including ulcerative colitis, Crohn's disease, and atopic dermatitis.

Etrasimod is an investigational compound that is not approved for any use in any country.

About Arena Pharmaceuticals

[Arena Pharmaceuticals](#) is driven to deliver novel, transformational medicines with optimized pharmacology to patients globally. Arena's proprietary pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility. [Etrasimod](#) (APD334), with potential utility in a broad range of immune-mediated inflammatory diseases, is being evaluated in later-stage clinical programs in inflammatory bowel disease (IBD), a Phase 2 program in atopic dermatitis (AD), as well as progressing programs for other potential indications. Arena is also evaluating [olorinab](#) (APD371) in a Phase 2 program for gastrointestinal pain. Arena continues to assess other earlier research and development stage drug candidates, including [APD418](#) for decompensated heart failure.

Arena has additional license agreements and partnerships, including with United Therapeutics (ralinepag in a Phase 3 program for pulmonary arterial hypertension), Everest Medicines Limited (etrasimod in Greater China and select Asian countries), Boehringer Ingelheim International GmbH (undisclosed target – preclinical), Outpost Medicine, LLC (undisclosed target – Phase 1), and Eisai Co., Ltd. and Eisai Inc. (BELVIQ® – marketed product).

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements may be identified by introductory words such as "evaluating", "progressing", "will", "advancing", "potential", "initiating", "confident that", "look forward to", "designed to", "driven to", "potentially", "being evaluated for", "assess", or words of similar meaning, or they may be identified by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, without limitation, statements about the following: the opportunity, development and potential of etrasimod, including regarding its design, its therapeutic potential in immune-mediated inflammatory diseases such as ulcerative colitis, Crohn's disease, and atopic dermatitis, its ability to treat atopic dermatitis, improve lives, and satisfy an unmet medical or clinical need, and its safety and efficacy; the ADVISE trial, including enrollment, study sites, trial design, and timing of Phase 2 data; the

significance of the ADVISE trial and its initiation; Arena's drive; and the potential of Arena's assets, programs, licenses, and partnerships, including to be first- or best-in-class or have broad clinical utility. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include: the timing and outcome of research, development and regulatory review is uncertain; enrolling subjects in our ongoing and intended clinical trials is competitive and challenging; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; nonclinical and clinical data are voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; clinical trials and other studies may not proceed at the time or in the manner expected or at all; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; risks related to unexpected or unfavorable new data; risks related to developing and commercializing drugs; risks related to relying on partners and other third parties; Arena's and third parties' intellectual property rights; and satisfactory resolution of litigation or other disagreements with others. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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