



Arena Pharmaceuticals Advancing Etrasimod Into Phase 3 Program in Atopic Dermatitis (AD), Reports Compelling Topline Results from Phase 2b ADVISE Trial

November 9, 2020

- **Etrasimod 2 mg in the primary analysis achieved statistical significance of the registrational endpoint vIGA at week 12**
- **Etrasimod 2 mg in the primary analysis demonstrated statistical significance in percent change in EASI, EASI-75, and pruritis at week 4**
- **Etrasimod did not meet the Ph 2b primary endpoint of EASI change from baseline at week 12**
- **Etrasimod 2 mg in the completer analysis for those with full therapeutic exposure achieved statistical significance in EASI percent change from baseline and vIGA at week 12**
- **Etrasimod was generally well tolerated, consistent with data in previous trials**
- **More than 80% of participants had vIGA 3 at baseline, indicative of a notably more-moderate population relative to contemporary trials**
- **Arena initiating a Phase 3 program in AD**
- **Arena to host conference call and webcast today at 4:30 PM ET (1:30 PM PT)**

SAN DIEGO, Nov. 9, 2020 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (Nasdaq: ARNA) today announced topline results from the Phase 2b ADVISE clinical trial evaluating etrasimod, a highly selective, once-daily, oral sphingosine 1-phosphate (S1P) receptor modulator, for the treatment of moderate-to-severe atopic dermatitis (AD).

"Today is an important day for Arena as we achieved our key objectives for the ADVISE trial which were to evaluate safety and efficacy of etrasimod in a dermatologic population, and to inform dose and design decisions for a pivotal Phase 3 program. We believe the clinical benefits of etrasimod in this trial were impressive, especially given the challenges of conducting a Phase 2 trial with a novel MOA in atopic dermatitis," stated Chris Cabell, MD, MHS, FACC, Executive Vice President, Head of Research and Development, and Chief Medical Officer at Arena. "We look forward to advancing etrasimod into a Phase 3 program in atopic dermatitis. We would like to thank the patients, trial coordinators and investigators who participated in this important trial."

In the ADVISE trial, the participants were representative of a moderate patient population (82.9% baseline vIGA 3) which constitutes upward of 40% of the AD market¹. In the primary analysis, nearly one-third of participants in the 2 mg etrasimod group achieved clear or almost clear skin, as defined by the validated Investigator Global Assessment (vIGA) – the FDA endpoint for Phase 3 registration. Importantly, the vIGA improvement was statistically significant vs. placebo at 12 weeks. Across the Eczema Area and Severity Index (EASI), EASI-75 and peak change in pruritis, etrasimod 2 mg demonstrated early and statistically significant effect at week 4. Etrasimod did not meet the Ph 2b primary endpoint of EASI change from baseline at week 12 as compared to placebo.

Overall, the 12-week study showed no plateau of effect, and the safety profile was consistent with previous trials of etrasimod including low first dose heart rate effect with no titration, and no serious adverse events (SAEs) across the groups. In the etrasimod groups, there were no cases of venous thromboembolic events, opportunistic or serious infections, macular edema, conjunctivitis, acne or herpes zoster. Additionally, none of the other adverse events commonly associated with first-generation S1P receptor modulators were seen in this trial.

Between weeks 4-8, the trial was impacted by unwarranted dose interruption (not related to drug safety) in 19% (n=9) of the etrasimod 2 mg group. Adjusting for this dose interruption – a post-hoc Completer Analysis with participants receiving full therapeutic exposure – etrasimod 2 mg showed statistically significant effect on the EASI score compared to placebo (weeks 4 and 12), EASI-75 at week 4, vIGA at week 12 and pruritis through week 8.

Importantly, the analysis of the participant cohort with dose interruption showed diminished clinical effect upon withdrawal and a recapture of effect upon reinstatement of study drug consistent with the pharmacodynamics (PD) of etrasimod.

Based on the compelling profile in this moderate AD population, etrasimod will be proceeding into a Phase 3 registrational program.

"I was encouraged by etrasimod's ability to demonstrate early differentiation from placebo and continued improvement to week 12 and a favorable safety profile. These data support moving forward to the next stage of clinical development," stated Emma Guttman, MD, PhD, Sol and Clara Kest Professor and the Incoming Chair at the Department of Dermatology, Director of the Center for Excellence in Eczema, and Director of the Laboratory of Inflammatory Skin Diseases at the Icahn School of Medicine at Mount Sinai Medical Center, New York.

"The results of the ADVISE trial are promising. In particular the efficacy as measured by improvement in vIGA will be important in determining the dose

and design of the Phase 3 registrational program," 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.

Arena plans to submit additional data from the ADVISE trial to future medical meetings and for publication in a peer-reviewed journal.

¹ DRG AD Disease Landscape & Forecast 2019; Barbarot S, 2018/ Ronmark E, 2012; Spherix Q2 2020 Report (physician survey)

Conference Call & Webcast Information

Arena will host a conference call and live webcast with the investment community today at 4:30 PM ET, to discuss the topline data

When: Monday, November 9, 2020, at 4:30 PM ET

Dial-in: (877) 643-7155 (United States) or (914) 495-8552 (International)

Conference ID: 6166976

Please join the conference call at least 20 minutes early to register. You can access the live webcast under the investor relations section of Arena's website at: www.arenapharm.com. Shortly after the call, a replay of the conference call will be archived under the events and presentations section of Arena's website and available for 30 days thereafter.

About ADVISE

ADVISE was a Phase 2b multicenter, randomized, double-blinded, placebo-controlled trial to assess the safety and efficacy of once-daily etrasimod in subjects with moderate-to-severe atopic dermatitis. The primary endpoint measured was percent change in Eczema Area and Severity Index (EASI) from baseline to week 12, followed by a 4-week follow-up observation period. Secondary endpoints include the proportion of participants achieving EASI-75, proportion of participants with a validated Investigator Global Assessment (vIGA) 0 to 1, and percent change in peak pruritis. The ADVISE trial enrolled approximately 140 subjects and was conducted in study sites across the United States, Canada and Australia. An open-label extension of the ADVISE trial is ongoing.

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 is intended to provide 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, eosinophilic esophagitis, atopic dermatitis, and alopecia areata.

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

About Arena Pharmaceuticals

[ARENA Pharmaceuticals](#) is a team with a singular purpose – deliver our important medicines to patients.

In a rapidly changing global market, we work with a sense of urgency every day to understand the needs of all our stakeholders, identify bold, sometimes disruptive, ideas to get our medicines to patients, and relentlessly execute until it's done.

ARENA - Care More. Act Differently.

Drs. Guttman and Silverberg are paid consultants of Arena.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements may be identified by words such as "believe," "look forward," "promising," "will," "plans," "may," "designed for," and "potential," and include, without limitation, statements about the following: Arena's plans to advance etrasimod into a Phase 3 registrational program in atopic dermatitis, the potential clinical benefits of etrasimod, Arena's plans to submit additional data from the ADVISE study for publication in a peer-reviewed journal, and Arena's purpose, work, understanding, ideas, and execution. 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, but are not limited to, the following: topline data may not accurately reflect the complete results of a particular study or trial; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner expected or at all; the timing and outcome of research, development and regulatory review is uncertain, and Arena's drug candidates may not advance in development or be approved for marketing; enrolling participants in Arena's ongoing and intended clinical trials is competitive and challenging; the duration and severity of the coronavirus disease (COVID-19) pandemic, including but not limited to the impact on Arena's clinical operations, the operations of Arena's suppliers, partners, collaborators, licensees, and capital markets, which in each case remains uncertain; risks related to developing and commercializing drugs; Arena will need additional funds to advance all of its programs, and you and others may not agree with the manner Arena allocates its resources; the impact of competition; risks related to unexpected or unfavorable new data; the risk that 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; satisfactory resolution of litigation or other disagreements with others; and risks related to the enforcement of Arena's and third parties' intellectual property rights. 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 (SEC), including but not limited to Arena's Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 27, 2020, and Arena's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, which was filed with the SEC on August 5, 2020. 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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