Arena Pharmaceuticals Presents Clinician and Patient Reported Outcomes Data from Phase 2b ADVISE Trial Evaluating Etrasimod in Adult Atopic Dermatitis During a Late-Breaking Session at American Academy of Dermatology VMX

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- Etrasimod 2 mg treatment group achieved statistical significance in the percentage change in weekly peak pruritis (PP-NRS), in the change in Dermatology Life Quality Index (DLQI), and in the change in Patient-Oriented Eczema Measure (POEM)

- Etrasimod 2 mg was generally well tolerated, consistent with data in previous trials

PARK CITY, Utah--(BUSINESS WIRE)--Apr. 23, 2021-- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced additional data at a late-breaking session at the American Academy of Dermatology VMX Experience. Etrasimod, a novel investigational drug candidate to treat moderate-to-severe atopic dermatitis (AD), demonstrated statistical significance in both clinician and patient reported outcomes in the etrasimod 2 mg treatment group of Arena's ADVISE Phase 2b clinical trial. Etrasimod is a highly selective, once-daily, oral sphingosine 1-phosphate (S1P) receptor modulator. Topline results from the ADVISE Phase 2b clinical trial were announced in November 2020. Today's results were presented by Emma Guttman-Yassky, MD, PhD, Waldman Professor and Chairwoman, The Kimberly and Eric J. Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai.

"Etrasimod demonstrated clinically meaningful improvements in both clinical signs of atopic dermatitis and patient reported outcomes in the etrasimod 2 mg treatment group," Dr. Guttman said. "Additionally, patient reported outcomes in this treatment group were improved as early as 2 weeks after etrasimod treatment was initiated. These results, combined with the fact that etrasimod was generally well-tolerated, are promising for this new mechanism of action for the treatment of atopic dermatitis."

In the ADVISE trial, Arena Pharmaceuticals evaluated the safety and efficacy of etrasimod in participants with moderate to severe eczema as well as to gain insight into design parameters for a potential pivotal Phase 3 program. Additionally, Arena quantified participants' assessments of etrasimod's efficacy using the peak pruritis numeric rating scale (PP-NRS), Dermatology Life Quality Index (DLQI) and Patient-Oriented Eczema Measure (POEM). Given the statistically significant and clinically meaningful improvements in PROs in the etrasimod 2 mg treatment group, coupled with the statistically significant improvements shown on the clinician-observed vIGA scale in the same treatment group, Arena Pharmaceuticals continues to expect to advance etrasimod into a pivotal registrational Phase 3 program for atopic dermatitis.

"The results reported today by Dr. Guttman-Yassky from the ADVISE trial have demonstrated impressive clinical benefit for patients living with moderate to severe atopic dermatitis," said Paul D. Streck, MD, Senior Vice President, Clinical Development, and Chief Medical Officer. "Together with a safety profile that was consistent with previous trials of etrasimod, we believe both the clinician-based assessments and the patient reported outcomes in the etrasimod 2 mg treatment group provide a strong basis to advance etrasimod to a global Phase 3 program as a potential treatment for atopic dermatitis. If approved, etrasimod has the potential to bring a novel, easily dosed oral therapy to patients who currently face limited treatment options for this chronic and debilitating disease."

Discussion of Trial

In the trial, 140 participants with chronic, moderate to severe eczema for at least a year were randomized into three equal cohorts for etrasimod 1 mg, etrasimod 2 mg, and placebo, treated once daily for 12 weeks. At the start of the trial, participants showed an Eczema Area and Severity Index (EASI) equal to or greater than 16, a vIGA score equal to 3 or more, and were affected by AD over 10% or more of their body surface. Of the etrasimod 2 mg participants, 29.8% successfully reduced their clinician-reported vIGA at 12 weeks to 0 or 1 (representing "clear" or "almost clear" skin) and improved by at least 2 points, compared to 13% for placebo (p=0.0450).

ADVISE also included three dermatology-specific patient reported outcomes. Participants gave regular evaluations of their peak pruritis numeric rating scale (PP-NRS), Dermatology Life Quality Index (DLQI) and Patient-Oriented Eczema Measure (POEM).

- For the PP-NRS, individuals in the etrasimod 2 mg cohort showed a statistically significant improvement as early as Week 2, compared to placebo, in their PP-NRS percentage score from baseline at the start of the trial; the etrasimod 2 mg cohort reported peak pruritis dropped 15.3% compared to a drop for placebo of only 1.0% (p=0.0380) at Week 4. This early dramatic drop suggests a rapid onset of action for etrasimod. The PP-NRS also dropped numerically a greater amount at Week 12 for the etrasimod 2 mg cohort (34.1%) than for the placebo cohort (23.9%) (p=0.1549).

- The DLQI measures overall impairment due to a dermatologic condition on a scale of 0 to 30, with 30 representing an extremely large effect on a patient's life. In assessing their overall DLQI, participants in the etrasimod 2 mg cohort saw statistically significant declines in their degree of impairment, dropping 7.6 points at Week 12 versus a drop of 4.2 points for placebo (p=0.0122).

- Arena believes the POEM patient-reported measure of etrasimod's efficacy also validated the investigational drug as a potential treatment for AD. The indexing of POEM indicates that as disease severity is reduced, the patient's life improves. In ADVISE, the etrasimod 2 mg cohort experienced an 8.4 point reduction versus 4 points for placebo (p=0.0045), results

that are both clinically and statistically significant.

Etrasimod was generally well-tolerated in ADVISE, and showed a safety profile that was consistent with previous trials of etrasimod. During the trial there were no serious adverse events or opportunistic or serious infections observed. The most common adverse events for participants of >5% and greater than placebo were nausea, constipation, back pain and dizziness.

Arena plans to submit data from the ADVISE trial for publication in a peer-reviewed journal.

Dr. Guttman-Yassky is a paid consultant and researcher for Arena Pharmaceuticals.

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 included 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. Etrasimod did not meet the primary endpoint of EASI change from baseline at week 12 as compared to placebo. A 52-week 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 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 medicines to patients, and relentlessly execute until it's done.

We are developing a richly diversified portfolio of therapeutic candidates targeting gastroenterology, dermatology, and cardiology. Our pipeline includes four investigational medicines in eight indications and eleven ongoing or planned clinical trials. To fuel our growth, we are unlocking the value of our historical GPCR research with a sustainable discovery engine for broad portfolio expansion.

ARENA - *Care More. Act Differently.*

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 "promising," "potential," "expects," "plan," "ongoing," "may," and "intended to," and include, without limitation, statements about the following: etrasimod's potential, including to advance into a Phase 3 program for atopic dermatitis, to be approved, to be a novel easily dosed oral therapy option for atopic dermatitis patients with limited treatment options, to provide systemic and local effects on specific immune cell types, and to treat multiple immune-mediated inflammatory diseases; Arena's plans to submit data from ADVISE for publication in a peer-reviewed journal; and Arena's purpose, work, understanding, ideas, execution, portfolio, pipeline, trials, and discovery engine. 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: 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; the duration and severity of the COVID-19 pandemic, including but not limited to its impact on Arena's clinical trials and operations, the operations of Arena's suppliers, partners, collaborators, licensees, and the capital markets, which in each case remains uncertain; risks related to developing and commercializing drugs; Arena may need additional funds to advance all of its programs; risks and uncertainties relating to cash and revenues that may be generated from product sales or other sources, including the impact of competition; risks related to unexpected or unfavorable new data; nonclinical and clinical data is 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; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline data may not accurately reflect the complete results of a particular study or trial; satisfactory resolution of litigation or other disagreements with others; government and third-party payor actions, including relating to reimbursement and pricing; risks related to relying on licenses or collaborative arrangements, including lack of control and potential disputes; the entry into or modification or termination of licenses or collaborative arrangements; and 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, 2020, which was filed with the SEC on February 23, 2021. 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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