



Arena Completes Full Enrollment of Etrasimod Phase 2 ADVISE Trial for Atopic Dermatitis, Provides Program Updates

May 26, 2020

- Phase 2b ADVISE trial evaluating etrasimod in atopic dermatitis (AD) enrollment complete, meeting the high end of targeted enrollment range, topline data expected Q4 2020**
- Etrasimod ELEVATE UC Program remains on track**
- Updated guidance for newly initiated trials, and certain trials in planning phase**

SAN DIEGO, May 26, 2020 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (Nasdaq: ARNA) today announced that it has completed full enrollment of the Phase 2b ADVISE trial evaluating etrasimod, an investigational next-generation, once-daily, oral, highly selective sphingosine 1-phosphate (S1P) receptor modulator, for the potential treatment of moderate-to-severe atopic dermatitis. The trial enrolled 140 patients at study sites across the United States, Canada and Australia, with a primary efficacy endpoint of percent change in Eczema Area and Severity Index (EASI) from baseline to week 12.

"Completing enrollment of the ADVISE trial is a significant milestone for Arena, and we are extremely proud that the team was able to meet the high end of our targeted enrollment range, particularly during these challenging times that our industry and society are facing," said Preston Klassen, M.D., M.H.S., Executive Vice President, Head of Research and Development of Arena. "Based on the potential best-in-class intrinsic properties of etrasimod, and clinical and non-clinical evidence seen to date, we are committed to driving its development in dermatologic conditions. We believe we have the potential to address the need for a safe and effective oral option for patients living with atopic dermatitis. We look forward to continuing with the execution of this Phase 2b trial and the expected availability of topline data by year end."

"We are very pleased that we have completed enrollment of our ADVISE trial and that to date we have kept timelines on track for our global Phase 3 program, ELEVATE UC. On other programs, we continue to see levels of disruption due to the COVID-19 pandemic; therefore, we are withdrawing our prior guidance on newly initiated trials and certain trials in the planning phase, including the evaluation of etrasimod in Crohn's disease, eosinophilic esophagitis, or EoE, and alopecia areata, or AA. We are hopeful that we can initiate both the EoE and AA studies this year and we are considering options for the Crohn's disease program to obtain Phase 2 dose-ranging data in 2021. Since the start of COVID-19, Arena has been vigilant and proactive in dealing with operational complexities due to the impact of this global pandemic," stated Amit D. Munshi, President and Chief Executive Officer of Arena. "Above all else, we will prioritize patient and employee safety. We intend to provide periodic updates as we gain additional clarity."

Program Updates:

- Etrasimod atopic dermatitis (AD) ADVISE Phase 2b trial enrollment completed; topline data expected Q4 2020
- Etrasimod ELEVATE UC 52 Phase 3 trial in ulcerative colitis (UC) ongoing and on track; ELEVATE UC 12 Phase 3 trial expected to initiate in H2 2020; topline data for both trials expected by year end 2021
- Etrasimod CULTIVATE Phase 2b dose-ranging trial in Crohn's disease (CD) initiated and ongoing; considering options to help facilitate availability of topline data in 2021; withdrawing previously announced overall program guidance based on expected COVID-19 impact on trial execution including site activation and enrollment
- Etrasimod eosinophilic esophagitis (EoE) Phase 2b and alopecia areata (AA) Phase 2 planning ongoing; initiation in 2020 dependent on COVID-19 situation in Q3/4
- Olorinab CAPTIVATE Phase 2b trial in abdominal pain associated with irritable bowel syndrome (IBS-C, IBS-D) ongoing; experiencing some COVID-19 related impact on trial enrollment; topline data expected between Q4 2020 and Q1 2021
- APD418 in acute heart failure (AHF) with Fast Track designation; Phase 1 trial experiencing COVID-19 related impact with trial temporarily paused; topline data expected Q4 2020

Etrasimod, olorinab, and APD418 are investigational compounds, not approved for any use in any country.

About Arena Pharmaceuticals

[ARENA Pharmaceuticals](#) is a team with a singular focus – 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

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 "expected," "will," "intend," "potential," "guidance," and include, without limitation, statements about the following: Arena's clinical programs, including clinical study site activations, enrollment of study subjects, patient safety, study momentum, drug supply, timing of data readouts, and potential future updates on Arena's clinical programs; Arena's ability to provide a safe and effective oral option for patients living with atopic dermatitis; and the potential of Arena's drug candidates, including potential best-in-class intrinsic properties. 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; enrolling patients in Arena's ongoing and intended clinical trials is competitive and challenging; the duration and severity of the recent 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 may need additional funds to advance all of its programs, and you and others may not agree with the manner Arena allocates its resources; risks and uncertainties relating to cash and revenues that may be generated from product sales or other sources, including the impact of competition; Arena's revenues are based in part on estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to Arena's guidance or previously reported results; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which was filed with the SEC on May 7, 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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