



Arena Pharmaceuticals Completes Full Enrollment of Etrasimod Phase 3 ELEVATE UC 52 Trial

February 2, 2021

- *Evaluating 2 mg etrasimod in study participants with moderately-to-severely active ulcerative colitis (UC)*
- *Topline data from ELEVATE UC 12 and UC 52 trials remain on track for Q1 2022*
- *Significant unmet need for safe and effective oral therapies in UC for patients with inadequate response, loss of response or intolerance to conventional or advanced therapies*

SAN DIEGO--(BUSINESS WIRE)--Feb. 2, 2021-- [Arena Pharmaceuticals, Inc.](#) (Nasdaq: ARNA) today announced that it has completed full enrollment of the Phase 3 ELEVATE UC 52 trial evaluating the safety and efficacy of etrasimod, a highly selective, once-daily, oral sphingosine 1-phosphate (S1P) receptor modulator, in participants with moderately-to-severely active ulcerative colitis. The trial enrolled 433 study participants in approximately 40 countries globally.

"Completion of UC 52 enrollment is the first important step in a comprehensive clinical program designed to potentially provide broad access and improve outcomes in patients with moderately-to-severely active ulcerative colitis. We thank our investigators, clinical site coordinators and especially the participants in the trial for enabling us to meet this important milestone," said Paul Streck, M.D., Senior Vice President, Clinical Development and Chief Medical Officer at Arena. "We expect topline data from both the ELEVATE UC 52 and UC 12 trials in Q1 2022, and we remain focused on successful clinical trial execution with careful attention to data integrity and the safety of the trial participants."

About ELEVATE UC 52

ELEVATE UC 52 is one of two pivotal trials that are part of the ELEVATE UC global Phase 3 registrational program. ELEVATE UC 52 is a 2:1 randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of etrasimod 2 mg once-daily in participants with moderately-to-severely active ulcerative colitis (UC) defined as a baseline 3-domain, modified Mayo Score of 4 to 9 with an endoscopic score of 2 or more, and a rectal bleeding score of 1 or more. This is a one-year trial evaluating clinical remission at 12 weeks, or induction, and at 52 weeks. The trial consists of a 28-day screening period, a 12-week treatment period, a 40-week treatment period, and a 2-week follow-up period. The primary objective of this trial is to assess the safety and efficacy of etrasimod on clinical remission after both 12 and 52 weeks. The primary endpoint is the FDA-required, 3-domain, modified Mayo Score, which is similar to the endpoint in the Phase 2 OASIS study of etrasimod in UC. Key secondary measures include the efficacy of etrasimod on clinical response, symptomatic response and remission, endoscopic changes, corticosteroid-free remission, and a total healing in these participants at time points up to 52 weeks of treatment. The ELEVATE UC program is being conducted in approximately 40 countries globally.

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.*

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 "designed to," "expect," "may," "lead to," and "potentially," and include, without limitation, statements about the potential benefits of the ELEVATE UC 52 trial, the timing of topline data from both the ELEVATE UC 52 and UC 12 trials, the potential benefits of etrasimod, 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: 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 and the operations of Arena's suppliers, partners, collaborators, and licensees, which in each case remains uncertain; risks related to developing and commercializing drugs; 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; 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 under the heading "Risk Factors" in Arena's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 9, 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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