



Arena Pharmaceuticals Achieves Target Enrollment for Etrasimod Phase 3 ELEVATE UC 52 Trial

December 8, 2020

- 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 on track for Q1 2022
- Due to the high number of participants currently in screening queue, screening to continue for an additional three weeks
- Significant unmet need for new and effective oral therapies in UC for patients with inadequate response, loss of response or intolerance to conventional or advanced therapies

SAN DIEGO, Dec. 8, 2020 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (Nasdaq: ARNA) today announced that it has achieved its targeted enrollment goal of 372 participants in the Phase 3 ELEVATE UC 52 trial evaluating the safety and efficacy of once-daily etrasimod, a highly selective, once-daily, oral sphingosine 1-phosphate (S1P) receptor modulator, in participants with moderately-to-severely active ulcerative colitis.

"We are pleased that we have achieved our target enrollment and maintained momentum, conduct, and timelines across the global ELEVATE UC program. While we have achieved our enrollment goal for the ELEVATE UC 52 trial, we have made the decision to extend screening an additional three weeks based on the high number of participants that we currently have in the screening queue. We continue to expect topline data from both the ELEVATE UC 52 and UC 12 trials in Q1 2022. We remain highly focused on successful clinical trial execution with careful attention to data integrity and the safety of the trial participants," stated Sheldon Sloan, MD, Vice President and Global Team Leader, Etrasimod, at Arena.

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. 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 over 400 sites across more than 40 countries.

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

Statements in this press release that are not statements of historical fact are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements may be identified by words such as "on track," "potential," "may," "expect," "objective," "designed for," and "intended to," and 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 UC, its ability to satisfy an unmet medical or clinical need, its potential effects, and its selectivity, safety, and activity; our expectation regarding the timing for topline data from the ELEVATE UC 12 and UC 52 trials; screening for the ELEVATE UC 52 trial remaining open for an additional three weeks; the significance of the ELEVATE UC 52 trial and its enrollment; 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, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which was 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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