Arena Pharmaceuticals Announces First Subject Dosed in ELEVATE UC 12 Global Phase 3 Trial Evaluating Etrasimod in Ulcerative Colitis

September 16, 2020

- Evaluating etrasimod 2 mg in patients with the clinical diagnosis of moderately to severely active ulcerative colitis (UC)

- Significant unmet need for new effective oral therapies in UC

SAN DIEGO, Sept. 16, 2020 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced that the first subject has been dosed in the ELEVATE UC 12 global Phase 3 trial evaluating etrasimod, an investigational, next-generation, once-daily, oral, selective sphingosine 1-phosphate (S1P) receptor modulator, for the potential treatment of moderately to severely active ulcerative colitis. ELEVATE UC 12 is the second of two pivotal trials within the Phase 3 ELEVATE UC registrational program to assess the safety and efficacy of etrasimod 2 mg.

"The enrollment of the first patient in ELEVATE UC 12 is an important milestone in the development of etrasimod, an oral, once-daily option, with a novel mechanism of action," stated Timothy Ritter, MD, Senior Medical Director, Department of Clinical Research and Education, GI Alliance Research. "There is a significant unmet need for patients with moderate to severe ulcerative colitis, and I look forward to seeing the results of Arena's Phase 3 program."

"We are pleased to initiate the ELEVATE UC 12 Phase 3 trial, the second of two pivotal trials that will bring us one step closer to our goal of delivering an oral, once-daily, durable therapeutic option for patients living with ulcerative colitis," stated Chris Cabell, MD, MHS, FACC, Executive Vice President, Head of Research and Development, and Chief Medical Officer at Arena. "This is a significant milestone for Arena as the progress confirms that the ELEVATE UC registrational program, including ELEVATE UC 12 and UC 52 trials, remains on track for data by year-end 2021."

About ELEVATE UC 12
ELEVATE UC 12 is one of two pivotal trials that are part of the ELEVATE UC global Phase 3 registrational program. ELEVATE UC 12 is a 2:1 randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of etrasimod 2 mg once-daily in subjects 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. The primary objective of this trial is to assess the safety and efficacy of etrasimod on clinical remission at 12 weeks assessed by the FDA-required, 3-domain, modified Mayo Score, which is similar to the primary endpoint in the Phase 2 OASIS trial. 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 subjects. The ELEVATE UC program is being conducted in approximately 450 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 provides 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, 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 "evaluating," "potential," "look forward to," "will," "goal," "on track to," and "may," 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 ulcerative colitis (UC), Crohn's disease, atopic dermatitis, and alopecia areata, its ability to satisfy an unmet medical or clinical need, and its safety and efficacy; the ELEVATE UC program and ELEVATE UC 52 and ELEVATE UC 12 trials, including enrollment, study sites and trial design; the significance of the trials and their initiation; 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; enrolling patients 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 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 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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