Arena Pharmaceuticals Announces First Subject Dosed in ELEVATE UC 52 Global Phase 3 Trial Evaluating Etrasimod in Ulcerative Colitis

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- Significant unmet need for new effective therapies exists in ulcerative colitis
- ELEVATE UC clinical trial sites continue to initiate

SAN DIEGO, June 17, 2019 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced that the first subject has been dosed in ELEVATE UC 52, the first of two pivotal trials within the Phase 3 ELEVATE UC registrational program evaluating etrasimod 2 mg in subjects with moderately to severely active ulcerative colitis (UC). ELEVATE UC 52 is a treat-through trial with a 12-week induction period followed by 40 weeks of maintenance. The ELEVATE UC registrational program aims to include more than 40 countries worldwide.

"We are pleased to enroll the first patient in the ELEVATE UC trial, supporting etrasimod's potential as an important future therapy for ulcerative colitis," stated Darshan Anandu, MD, Gastroenterology, G.I. Specialists of Houston. "With 60-80% of patients either not receiving or failing on the current standard of care, there is a clear and significant need for innovative options, especially orally-delivered treatments."

"We are thrilled to announce the first patient dosed in the ELEVATE UC 52 trial. The etrasimod data seen to date are highly encouraging, and we believe represent a clear readthrough to our ELEVATE UC pivotal program, providing us confidence that it will demonstrate clinically meaningful and market-leading evidence of efficacy and safety," stated Preston Klassen, MD, MHS, Executive Vice President, Research and Development and Chief Medical Officer of Arena. "Initiating this trial is the next step towards bringing a potential game-changing therapy to UC patients globally. We are very grateful to the patients who have participated in etrasimod clinical trials thus far, and to the many additional patients who will enroll in the ELEVATE UC program. We also thank the physicians, medical professionals, and site coordinators, for their continued support."

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 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. 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 primary 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 subjects at time points up to 52 weeks of treatment. The ELEVATE UC program will be conducted in approximately 450 sites across more than 40 countries.

About Etrasimod
Etrasimod (APD334), is a next generation, oral, selective sphingosine 1 phosphate (S1P) receptor modulator, discovered by Arena, designed to provide systemic and local cell modulation by selectively targeting S1P receptor subtypes 1, 4 and 5. Etrasimod has therapeutic potential in immune and inflammatory-mediated diseases such as ulcerative colitis, Crohn's disease, and atopic dermatitis. S1P receptors have been demonstrated to be involved in the modulation of several biological responses, including lymphocyte trafficking from lymph nodes to the peripheral blood. By isolating subpopulations of lymphocytes in lymph nodes, fewer immune cells are available in the circulating blood to effect tissue damage.

Etrasimod is an investigational compound that is not approved for any use in any country.

About Arena Pharmaceuticals
Arena Pharmaceuticals is driven to deliver novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Arena's proprietary pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility. Etrasimod (APD334), with potential utility in a broad range of immune and inflammatory conditions, is being evaluated in later-stage clinical programs in ulcerative colitis (UC) and Crohn's disease, as well as in programs for other indications such as atopic dermatitis. Arena is also evaluating olorinab (APD371) in a Phase 2 program for gastrointestinal pain. Arena continues to assess other earlier research and development stage drug candidates, including APD418 for decompensated heart failure.

Arena has additional license agreements and partnerships, including with United Therapeutics (ralinepag in a Phase 3 program for pulmonary arterial hypertension), Everest Medicines Limited (etrasimod in Greater China and select Asian countries), Boehringer Ingelheim International GmbH (undisclosed target – preclinical), Outpost Medicine, LLC (undisclosed target – preclinical), and Eisai Co., Ltd. and Eisai Inc. (BELVIQ® – marketed product).

Forward-Looking Statements
Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements may be accompanied by words such as "aims to," "potential," "future," "believe," "confidence that," "will," "step towards," "objective," "designed to," "driven to," "potentially," "being evaluated for," "evaluating for," "assess for," or words of similar meaning, or they may be identified by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, without limitation, statements about the following: the opportunity, development and potential of etrasimod, including to be an important future therapy, be game-changing, or satisfy an unmet medical need; the potential of prior etrasimod data, including to represent a clear readthrough to the ELEVATE UC pivotal program; the potential of the ELEVATE UC program, including to demonstrate clinically meaningful and market-leading evidence of etrasimod's efficacy and safety; Arena's

drive; and the potential of Arena's assets, programs, licenses, and collaborations, including to be first- or best-in-class or have broad clinical utility. 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: the timing and outcome of research, development and regulatory review is uncertain; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; nonclinical and clinical data are 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; clinical trials and other studies may not proceed at the time or in the manner expected or at all; enrolling patients in our ongoing and intended clinical trials is competitive and challenging; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; risks related to unexpected or unfavorable new data; risks related to developing and commercializing drugs; risks related to relying on partners and other third parties; Arena's and third parties' intellectual property rights; and satisfactory resolution of litigation or other disagreements with others. 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 its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. 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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