Arena Pharmaceuticals Reports Positive Long-Term Data from the Open-Label Extension of the Phase 2 OASIS Trial Evaluating Etrasimod for Treatment of Ulcerative Colitis

January 7, 2019

- Etrasimod demonstrated clinical response and durable, long-term clinical remission
- Etrasimod demonstrated favorable long-term safety and tolerability

SAN DIEGO, Jan. 7, 2019 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced positive data from the open-label extension (OLE) of the Phase 2 OASIS trial of its investigational drug candidate etrasimod, a next-generation, oral, selective sphingosine 1 phosphate (S1P) receptor modulator in development for the treatment of moderate to severely active ulcerative colitis (UC). Overall, etrasimod demonstrated durable, long-term clinical remission and was generally safe and well tolerated in this trial.

Open-Label Extension of Phase 2 OASIS Trial Design
This was a 34-week open-label extension evaluating the long-term safety, tolerability and efficacy of etrasimod in 118 subjects (84% of OASIS study completers) who completed the 12-week Phase 2 OASIS randomized, placebo-controlled trial. Of the 118 subjects, 105 received only 2 mg etrasimod during the OLE study regardless of previous study treatment. Key efficacy measurements included clinical response, clinical remission, and endoscopic improvement at end of treatment (46 weeks).

Key Efficacy Measurements
Of the subjects who completed 2 mg etrasimod treatment during the OLE study (n=84), 79% achieved clinical response, 39% achieved clinical remission, and 51% had endoscopic improvement at the end of the OLE study.

For OLE study completers who received 2 mg etrasimod in the original Phase 2 OASIS trial (n=22), 82% experienced clinical response, 50% were in clinical remission, and 55% had endoscopic improvement at the end of the OLE study.

Among subjects achieving clinical response or clinical remission on 2 mg etrasimod at 12 weeks in OASIS, sustained treatment effect over 46 weeks was observed, with 93% experiencing sustained clinical response and 75% experiencing sustained clinical remission at both 12 and 46 weeks.

Key Safety Measurements
Etrasimod demonstrated a favorable long-term safety profile; adverse events in the OLE study were generally mild to moderate in severity and no new safety findings were noted. Impact on heart rate and atrioventricular (AV) conduction was minimal throughout the study with no discontinuations from study related to bradycardia or AV block.

The Company plans to present full study results at future medical congresses.

"We are pleased with the long-term safety and efficacy that etrasimod has demonstrated in the open-label extension of our Phase 2 OASIS trial," said Preston Klassen, MD, MHS, Executive Vice President, Research and Development and Chief Medical Officer of Arena. "These data further support our belief in etrasimod as an important future therapy in inflammatory bowel disease and our strong commitment to improve the lives of patients suffering from these grievous conditions."

"There remains a significant unmet need for new oral therapies for ulcerative colitis. It is encouraging to see longer-term safety and tolerability data and durable treatment effects of etrasimod, which are important for patients suffering from this chronic condition," said Bruce E. Sands, MD, Mount Sinai Hospital and the Icahn School of Medicine, Mt. Sinai, New York. "These results further support the initiation of the Phase 3 clinical development program to further evaluate etrasimod in ulcerative colitis."

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, primary biliary cholangitis (PBC) 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 primary biliary cholangitis (PBC) and atopic dermatitis. Ralinepag (APD811) is being evaluated in a Phase 3 program for pulmonary arterial hypertension (PAH). 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.

In addition, Arena has several partnerships including with Everest Medicines Limited (ralinepag and 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 identified by introductory words such as "evaluating," "in development for," "belief," "future," "commitment to," "designed to," "potential," "driven to," "potentially," "being evaluated for," or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, without limitation, statements regarding the intention and plan to progress etrasimod's development; etrasimod's potential, including to be an important future therapy in inflammatory bowel disease, to satisfy a significant unmet medical need, to have utility in a broad range of immune and inflammatory-mediated diseases such as ulcerative colitis, Crohn's disease, PBC, and atopic dermatitis, and to modulate several biological responses, including lymphocyte trafficking from lymph nodes to the peripheral blood; Arena's drive; and the potential of Arena's assets, programs, and collaborations. 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, without limitation, the following: the announced data are based on an interim analysis of certain key measurements, and such interim data or analysis may change following a more comprehensive review of the data, and such interim data or analysis may not accurately reflect the final results of the study; the reported-on trial was not a placebo-controlled study; 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; the timing and outcome of research, development and regulatory review is uncertain; 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; 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; 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 Arena's 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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