



November 10, 2017

Arena Pharmaceuticals Completes Full Enrollment in Etrasimod Phase 2 Clinical Study for Ulcerative Colitis

Data Readout Expected in Q1 2018

SAN DIEGO, Nov. 10, 2017 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (NASDAQ: ARNA), today announced that it has completed full enrollment in the etrasimod Phase 2 study in ulcerative colitis (UC). Etrasimod is an investigational-stage, oral, next-generation, sphingosine-1-phosphate (S1P) receptor modulator with improved pharmacology and pharmacokinetics intended for the treatment of autoimmune diseases. The study enrolled 157 patients at sites globally.

"A significant unmet need exists across a range of autoimmune conditions including UC, and we are excited to have fully enrolled this study for etrasimod, meeting the high-end of our targeted range," said Preston Klassen, M.D., MHS, Executive Vice President, Research and Development and Chief Medical Officer of Arena. "We look forward to the availability of data from this Phase 2 trial in the first quarter of 2018. Given etrasimod's oral route of administration and optimized profile, we believe it has the potential to deliver broad clinical utility."

The study is a 12-week, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging trial evaluating safety and tolerability. Efficacy endpoints include improvement in the Mayo clinical score (3-component, total), response, remission and mucosal healing versus placebo, and dose response. The study enrolled patients with moderate to severe UC (3-component Mayo score of 4-9 that includes endoscopic sub score > 2, rectal bleeding score > 1).

About Etrasimod

Etrasimod (APD334), is an oral, next generation, 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, while avoiding subtypes 2, 3. Etrasimod exhibits potentially best in class pharmacokinetics and pharmacodynamics with rapid onset of action and rapid recovery of t-lymphocytes. Selective binding with S1PR1 is believed to inhibit a specific subset of activated lymphocytes from migrating to sites of inflammation. The result is a reduction of circulating T and B lymphocytes that leads to anti-inflammatory activity. Importantly, immune surveillance is maintained. The receptor subtypes 4, 5 exhibit similar activity on additional proliferating immune cell types. Optimized pharmacology and pharmacokinetics may allow superior clinical utility across a broad range of autoimmune conditions.

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

About Autoimmune Diseases

Autoimmune diseases are characterized by an inappropriate immune response against substances and tissues that are normally present in the body. In an autoimmune reaction, a person's antibodies and immune cells target healthy tissues, triggering an inflammatory response. Reducing the immune and/or inflammatory response is an important goal in the treatment of autoimmune disease.

About Ulcerative Colitis

Ulcerative colitis is a chronic disease that affects the large intestine. The innermost lining of the large intestine becomes inflamed and ulcers may form on the surface, which can cause symptoms such as frequent bowel movements, diarrhea and bloody stools. The inflammation is usually found in the rectum and can include all or a portion of the colon. Currently available treatment options have limitations in terms of side effects, patient response, efficacy and administration. We believe that an effective, oral, selective S1P receptor modulator that provides clinical benefits without current limitations has the potential to improve treatment for patients with ulcerative colitis.

About Arena Pharmaceuticals

[Arena Pharmaceuticals](#) is a biopharmaceutical company focused on developing novel, small molecule drugs with optimized receptor pharmacology designed to deliver broad clinical utility across multiple therapeutic areas. Our proprietary pipeline includes potentially first- or best-in-class programs for which we own global commercial rights. Our three most advanced investigational clinical programs are [ralinepag](#) (APD811) which has completed a Phase 2 trial for pulmonary arterial hypertension (PAH), [etrasimod](#) (APD334) in Phase 2 evaluation for multiple autoimmune indications, and [APD371](#) in Phase

2 evaluation for the treatment of pain associated with Crohn's disease. In addition, Arena has collaborations with the following pharmaceutical companies: Eisai Co., Ltd. and Eisai Inc. (commercial stage), Axovant Sciences (Phase 2 candidate), and Boehringer Ingelheim International GmbH (preclinical candidate).

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 "expected," "intended," "look forward to," "believe," "potential," "become," "believed to," "may," "can," "focused on," "designed to," 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 about the ongoing Phase 2 program for etrasimod; the ability to complete planned trials of etrasimod; the expected timing of clinical data; the potential of etrasimod, including to improve treatment of UC patients, to deliver clinical utility across a range of autoimmune conditions and to become a disease modifying therapy; the potential of Arena's drugs and drug candidates; and Arena's focus, 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 the following: enrolling patients in our ongoing and intended clinical trials is competitive and challenging; clinical trials and other studies may not proceed at the time or in the manner expected or at all; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; the timing and outcome of research, development and regulatory review is uncertain; topline data may not accurately reflect the complete results of a particular study or trial; 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; unexpected or unfavorable new data; risks related to developing and commercializing drugs; 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; the risk that Arena's revenues are based in part on estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to Arena's guidance or previously reported results; government and third-party payor actions, including relating to reimbursement and pricing; risks related to relying on collaborative arrangements; the entry into or modification or termination of collaborative arrangements; 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, including but not limited to our Annual Report on Form 10-K which was filed on March 15, 2017 and our Quarterly Report on Form 10-Q which was filed on November 8, 2017. 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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