



Arena Pharmaceuticals Reports Positive Phase 2 Results from the OASIS Trial for Etrasimod in Patients with Ulcerative Colitis

March 19, 2018

- **OASIS trial met primary and all secondary endpoints with statistical significance for patients receiving 2 mg dose of etrasimod for 12 weeks**
- **The 2 mg etrasimod group achieved statistically significant improvement in clinical remission**
 - **Safety results support potential best-in-class profile**
 - **Arena intends to initiate a Phase 3 program in ulcerative colitis**
- **Investor conference call and webcast today at 4:30 p.m. EDT (1:30 p.m. PDT)**

SAN DIEGO, March 19, 2018 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (NASDAQ: ARNA), today announced positive topline Phase 2 results from the OASIS trial for etrasimod, an investigational, once-daily, orally administered, selective sphingosine 1-phosphate (S1P) receptor modulator in development for the treatment of ulcerative colitis (UC). Patients receiving the 2 mg dose of etrasimod achieved statistically significant improvements versus placebo in the primary, all secondary, and clinical remission endpoints.

Relative to placebo, there was a statistically significant ($p = 0.009$) 0.99 point improvement in a 3-component (stool frequency, rectal bleeding and findings on endoscopy) Mayo Clinic Score (ranging from 0 to 9) with etrasimod 2 mg at week 12. In the 1 mg group, there was a 0.43 point improvement in 3-component Mayo Clinic Score at week 12 relative to placebo, which was not statistically significant ($p = 0.146$). Significantly more patients in the etrasimod 2 mg group achieved endoscopic improvement compared with placebo (41.8% vs. 17.8%, $p = 0.003$).

The proportion of patients achieving clinical remission, defined by the 3-component Mayo Clinic Score, was 33.0% in the etrasimod 2 mg group compared to 8.1% for the placebo group ($p < 0.001$). Remission as defined by the 4-component Total Mayo Clinic Score was 24.5% and 6.0% for etrasimod 2 mg and placebo, respectively ($p = 0.004$).

Etrasimod was well tolerated and there were fewer patients with serious adverse events (SAEs) compared to placebo (0% in 2 mg, 5.8% in 1 mg and 11.1% in placebo). Impact on heart rate and atrioventricular (AV) conduction was low throughout the study with no discontinuations from study related to bradycardia or AV block. There were no increases in liver function tests compared to placebo and no reports of macular edema or pulmonary function test abnormalities. The Company plans to present full study results at future medical congresses.

"The results of this Phase 2 trial are impressive and demonstrate statistically significant efficacy of orally administered etrasimod, including clinically meaningful improvement in remission, as well as endoscopic improvement in what has been historically referred to as mucosal healing," said William Sandborn, M.D., Professor of Medicine and Chief, Division of Gastroenterology and Director, University of California San Diego Inflammatory Bowel Disease Center. "Despite recent advances in treatment options, there remains a significant unmet need for new oral therapies for ulcerative colitis. I look forward to etrasimod advancing into a Phase 3 program."

Preston Klassen, M.D., M.H.S., Executive Vice President, Research and Development and Chief Medical Officer of Arena Pharmaceuticals, said, "We believe these data support proceeding to a Phase 3 program in ulcerative colitis and continuing efforts to understand the broad potential utility of etrasimod in other immune and inflammatory diseases with significant unmet needs. Along with the positive Phase 2 results for ralinepag reported last year, this important milestone for the Company further amplifies our conviction in Arena's internally discovered and developed compounds and their potential to be best-in-class."

Conference Call & Webcast Information

Arena will host a conference call and live webcast with the investment community today, March 19, 2018, at 4:30 p.m. EDT to discuss the study results and provide a corporate update.

When: March 19, 2018, 4:30 p.m. EDT

Dial-in: (877) 643-7155 (United States) or (914) 495-8552 (International)

Conference ID: 7299327

Please join the conference call at least 10 minutes early to register. You can access the live webcast under the investor relations section of Arena's website at: www.arenapharm.com. A replay of the conference call will be archived under the [investor relations](#) section of Arena's website for 30 days shortly after the call.

About OASIS

OASIS was a randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study to assess safety and efficacy of two orally administered doses (1 mg and 2 mg) of etrasimod in patients with ulcerative colitis (UC) across 71 sites in 16 countries. The OASIS trial randomized 156 patients, with moderate to severe UC (3-component Mayo Clinic Score of 4-9 with an endoscopic subscore ≥ 2 and a rectal bleeding score ≥ 1). The pre-specified statistical analysis plan applied one-sided testing, in which conventional statistical significance is achieved at p -values < 0.025 .

About Etrasimod

Etrasimod (APD334), is an oral, once-daily, next generation, selective sphingosine 1-phosphate (S1P) receptor modulator, discovered by Arena, designed to provide systemic and local cell modulation by targeting S1P receptor subtypes 1, 4 and 5, while avoiding subtypes 2 and 3. Etrasimod is believed to exhibit potentially best-in-class pharmacokinetics and pharmacodynamics with rapid onset of action and rapid recovery of T lymphocytes. Selective binding with S1P receptor subtype 1 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 while immune surveillance is maintained. The receptor subtypes 4 and 5 exhibit similar activity on additional proliferating immune cell types. Optimized pharmacology and pharmacokinetics may allow improved clinical utility across a broad range of immune and inflammatory conditions.

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

About Arena Pharmaceuticals

[Arena Pharmaceuticals](#) is focused on developing novel, small molecule drugs with optimized receptor pharmacology and pharmacokinetics designed to deliver broad clinical utility across several therapeutic areas. Arena's proprietary pipeline includes potentially first- or best-in-class programs. The most advanced investigational clinical programs are [ralinepag](#) (APD811), which is anticipated to commence a Phase 3 program for pulmonary arterial hypertension (PAH), and [etrasimod](#) (APD334), for which the Company intends to commence a Phase 3 program for ulcerative colitis (UC) and which the Company believes has potential utility for a broad range of immune and inflammatory conditions. Arena is also evaluating [APD371](#) in Phase 2 for the treatment of pain associated with Crohn's disease. In addition, Arena has collaborations with the following pharmaceutical companies: Everest Medicines Limited (ralinepag and etrasimod in Greater China and select Asian countries), Axovant Sciences GmbH (nelotanserin - Phase 2), Boehringer Ingelheim International GmbH (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 "potential," "plans," "look forward to," "promise," "will," "can," "designed to," "believed to," "may," "focused on," "being evaluated for," "expected," "intended," "potentially," "goal," "believe," 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 importance of etrasimod's Phase 2 data; etrasimod's potential to be a best-in-class treatment in UC and to have broad utility in other immune and inflammatory diseases with significant unmet needs; plans for etrasimod's Phase 3 development; publication plans; and Arena's focus, goals, strategy, clinical 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: the topline data is based on preliminary analysis of key data, and such data or analysis may change following a more comprehensive review of the data, and such topline data may not accurately reflect the complete results of a particular study or trial; 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 our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on March 14, 2018. 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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