July 10, 2017

Arena Pharmaceuticals Reports Positive Topline Phase 2 Results for Ralinepag in Patients with Pulmonary Arterial Hypertension

- Primary efficacy analysis successful - significant improvement in pulmonary vascular resistance
- Safety data consistent with other drugs acting through the prostacyclin receptor-mediated effects
- Management to host conference call and webcast today at 4:30 p.m. EDT

SAN DIEGO, July 10, 2017 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (NASDAQ: ARNA), today announced positive Phase 2 results for ralinepag, an investigational, long-acting, orally administered prostacyclin receptor agonist under development for the treatment of pulmonary arterial hypertension (PAH). In this 61-patient study, the primary efficacy analysis demonstrated a statistically significant absolute change from baseline in pulmonary vascular resistance (PVR) compared to placebo. Ralinepag also demonstrated numerical improvement in 6-minute walk distance (6MWD).

Ralinepag improved median PVR by 163.9 dyn.s.cm^{-5} from baseline compared to a 0.7 dyn.s.cm^{-5} worsening from baseline in the placebo arm (P=0.02). Patients treated with ralinepag had a 29.8% improvement in PVR compared to the placebo arm (P=0.03) and a 20.1% improvement in PVR compared to baseline. Additionally, adverse events observed in the study were consistent with other prostacyclin treatments for the management of PAH, with headache, nausea, diarrhea, jaw pain and flushing being the most commonly reported adverse events. The company plans to present full study results at future medical congresses.

"The positive outcome of this Phase 2 trial in a contemporary PAH patient population is an important milestone in the development of ralinepag for the treatment of patients suffering from this grievous illness," stated Preston Klassen, M.D., MHS, Executive Vice President, Research and Development and Chief Medical Officer of Arena. "It is exciting to see the positive nonclinical pharmacological profile translating into potentially the first oral prostacyclin therapy that may approach consistent therapeutic levels without the complexity of parenteral (IV) therapy. These data give us confidence to move expeditiously toward a Phase 3 clinical program."

Vallerie McLaughlin, M.D., Kim A. Eagle MD Endowed Professor of Cardiovascular Medicine at the University of Michigan and Director of the Pulmonary Hypertension Program, added, "PAH is a complex and serious disease, often with a poor prognosis despite the use of currently available treatments. New therapeutic options to manage patients with PAH are needed. The results of this Phase 2 study of ralinepag, in patients already receiving, in most cases, multiple background therapies, showed a clinically meaningful improvement in PVR, a well-established indicator of treatment benefit, believed to be correlated with long-term clinical outcomes in patients with PAH."

Conference Call & Webcast Information
The Arena management team will host a conference call and live webcast with slides with the investment community today, Monday, July 10, 2017, at 4:30 p.m. EDT to discuss the information in this press release.

When: July 10, 2017, 4:30 p.m. EDT
Dial-in: (877) 643-7155 (United States) or (914) 495-8552 (International)
Conference ID: 52490461

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 the Trial
The Phase 2 study was a randomized, double-blind, placebo-controlled, dose-ranging study in 61 adult patients with PAH, WHO/NYHA functional class II-IV. Study medication was titrated over 9 weeks, followed by a 13-week treatment period. The primary efficacy analysis was absolute change from baseline in pulmonary vascular resistance (PVR) at week 22. Additional endpoints included change from baseline in 6-minute walk test, proportion of subjects who exhibit clinical worsening and

safety and tolerability. Patients who completed week 22 could transition to an open-label ralinepag extension study.

About Ralinepag
Ralinepag (APD811) is an oral, next-generation, selective IP receptor agonist targeting the prostacyclin pathway and intended for the treatment of pulmonary arterial hypertension (PAH). Arena discovered and developed this drug candidate internally. Ralinepag's potency on vasodilation, inhibition of proliferation of vascular smooth muscle cells, and inhibition of platelet aggregation, combined with an extended half-life support its application as a potentially best-in-class agent for the treatment of PAH. Ralinepag is an investigational compound that is not approved for any use in any country.

About Pulmonary Arterial Hypertension
Pulmonary Arterial Hypertension (PAH) is a rare, chronic, progressive, life-threatening disorder characterized by increased pressure in the arteries that carry blood from the heart to the lungs. The increased pressure strains the heart, which can limit physical activity, result in heart failure and reduce life expectancy. Current treatment of PAH falls within four distinct therapeutic classes: endothelin receptor antagonists (ERAs), phosphodiesterase-5 (PDE-5) inhibitors, prostacyclin analogues and soluble guanylate cyclase (SGc) stimulators. The available therapies have positive effects in PAH, but they do not provide a cure, and in many patients the disease will progress despite treatment.

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 Phase 2 evaluation for pulmonary arterial hypertension (PAH), etrasimod (APD334) in Phase 2 evaluation for multiple autoimmune indications including ulcerative colitis (UC), 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 statements may be identified by introductory words such as "may," "expects," "plan," "believe," "will," "achieve," "anticipate," "would," "should," "subject 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 statements regarding the importance of ralinepag's Phase 2 data, ralinepag's potential and plans for ralinepag's Phase 3 development; and Arena's focus, goals, strategy and clinical programs. 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: top-line 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; clinical and nonclinical 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; 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; risks related to developing, seeking regulatory approval and commercializing drugs; unexpected or unfavorable new data; Arena's and third parties' intellectual property rights; clinical trials and other studies may not proceed at the time or in the manner expected or at all; data and information related to our programs may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review, partnering or approval; competition; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and their availability and use; reimbursement and pricing decisions; risks related to relying on partners and other third parties; and satisfactory resolution of litigation or other disagreements; and those factors disclosed in Arena's filings with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended March 31, 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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View original content:http://www.prnewswire.com/news-releases/arena-pharmaceuticals-reports-positive-topline-phase-2-results-for-ralinepag-in-patients-with-pulmonary-arterial-hypertension-300485483.html

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