Arena Pharmaceuticals Announces Orphan Drug Designation for Etrasimod for the Treatment of Eosinophilic Esophagitis (EoE)

June 9, 2021

– EoE affects approximately 135,000 in the US and an estimated 132,000 patients in the EU4 and United Kingdom

– Currently no FDA approved therapies in the US for the treatment of EoE

PARK CITY, Utah--(BUSINESS WIRE)--Jun. 9, 2021-- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation status to etrasimod, a highly selective, once-daily, oral sphingosine 1-phosphate (S1P) receptor modulator, for the treatment of eosinophilic esophagitis (EoE).

Etrasimod is being investigated in the Phase 2b VOYAGE trial, a randomized, double-blind, placebo-controlled trial, with a primary efficacy measurement at week 16 and a secondary efficacy analysis at week 24, to assess the safety and efficacy of 1 mg and 2 mg etrasimod in approximately 100 participants with EoE.

“The granting of Orphan Drug Designation for etrasimod for EoE is not only good news for Arena, but more importantly for the patients living with EoE, as there are currently no FDA approved therapies for this patient population,” said Paul Streck, MD, Senior Vice President and Chief Medical Officer of Arena. “We look forward to our continued collaboration with our investigators participating in the Phase 2b VOYAGE trial and the FDA as we strive to bring a potentially important therapy to these patients.”

About Etrasimod

Etrasimod (APD334) is a next generation, once-daily, oral, highly selective sphingosine 1-phosphate (S1P) receptor modulator discovered by Arena and designed for optimized pharmacology and engagement of S1P receptors 1, 4, and 5, which may lead to an improved efficacy and safety profile. Etrasimod is intended to provide systemic and local effects on specific immune cell types and has the potential to treat multiple immune-mediated inflammatory diseases including ulcerative colitis, Crohn’s disease, eosinophilic esophagitis, atopic dermatitis, and alopecia areata.

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

About Arena Pharmaceuticals

ARENA Pharmaceuticals is a team with a singular purpose – deliver important medicines to patients.

In a rapidly changing global market, we work with a sense of urgency every day to understand the needs of all our stakeholders, identify bold, sometimes disruptive, ideas to get medicines to patients, and relentlessly execute until it's done.

We are developing a richly diversified portfolio of therapeutic candidates targeting gastroenterology, dermatology and cardiology. Our pipeline includes four investigational medicines in eight indications and eleven ongoing or planned clinical trials. To fuel our growth, we are unlocking the value of our historical GPCR research with a sustainable discovery engine for broad portfolio expansion.

ARENA - *Care More. Act Differently.*

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements may be identified by words such as "evaluating," "look forward to," "potential," "designed for," "may," and "intended," and include, without limitation, statements about the following: the significance and potential benefits of etrasimod's Orphan Drug Designation for EoE; the opportunity, development and potential of etrasimod, including regarding its design, its safety and efficacy, its therapeutic potential in EoE, and its ability to satisfy an unmet medical or clinical need; the Phase 2b VOYAGE trial, including study significance, enrollment, study sites, trial design, and timing of data; and Arena's purpose, work, understanding, ideas, execution, portfolio, pipeline, and discovery engine. 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, but are not limited to, the following: clinical trials and other studies may not proceed at the time or in the manner expected, or at all; the timing and outcome of research, development and regulatory review is uncertain, and Arena's drug candidates may not advance in development or be approved for marketing; enrolling patients in Arena's ongoing and intended clinical trials is competitive and challenging; the duration and severity of the coronavirus disease (COVID-19) pandemic, including but not limited to its impact on Arena's clinical trials and operations, the operations of Arena's suppliers, partners, collaborators, licensees, and the capital markets, which in each case remains uncertain; risks related to developing and commercializing drugs; Arena may need additional funds to advance all of its programs; risks and uncertainties relating to cash and revenues that may be generated from product sales or other sources, including the impact of competition; risks related to unexpected or unfavorable new data; nonclinical and clinical 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 before or after approval; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; topline data may not accurately reflect the complete results of a particular study or trial; satisfactory resolution of litigation or other disagreements with others; government and third-party payor actions, including relating to reimbursement and pricing; risks related to relying on licenses or collaborative arrangements, including lack of control and potential disputes; the entry into or modification or termination of licenses or collaborative arrangements; and Arena's and third parties' intellectual property rights. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, which was filed with the SEC on May 5, 2021. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210609005522/en/

Patrick Malloy
Arena Pharmaceuticals, Inc.
Vice President, Investor Relations & Corporate Communications
pmalloy@arenapharm.com
847.987.4878

Source: Arena Pharmaceuticals, Inc.