Arena Pharmaceuticals Announces First Subject Dosed in Phase 2 Trial Evaluating Etrasimod in Alopecia Areata

September 1, 2020

- Evaluating etrasimod 2 mg in patients with the clinical diagnosis of moderate-to-severe alopecia areata

- There are currently no FDA-approved treatments for alopecia areata

SAN DIEGO, Sept. 1, 2020 /PRNewswire/ -- Arena Pharmaceuticals, Inc. (Nasdaq: ARNA) today announced that the first subject has been dosed in a Phase 2 trial evaluating etrasimod, an investigational, next-generation, once-daily, oral, selective sphingosine 1-phosphate (S1P) receptor modulator, for the potential treatment of moderate-to-severe alopecia areata. The randomized, placebo-controlled trial will evaluate the efficacy and safety of etrasimod 2 mg for 24 weeks in 36 subjects in sites across the United States and Canada.

"It is exciting to see the clinical advancement of an oral agent with a novel mechanism of action for the potential treatment of alopecia areata," stated Brett King, MD, PhD, Associate Professor of Dermatology, Yale School of Medicine. "With no currently FDA-approved treatment options there is a significant unmet medical need in alopecia areata. I see patients suffer tremendous emotional and psychosocial distress and reduced quality of life as a result of this disease. I look forward to seeing the progress of Arena's Phase 2 program and the development of etrasimod."

"Dosing the first patient in our Phase 2 alopecia areata trial is a great accomplishment for the team, furthering our expansion into dermatology," stated Chris Cabell, MD, MHS, FACC, Executive Vice President, Head of Research and Development, and Chief Medical Officer at Arena. "To date, we have seen preclinical and scientific validation supporting the rationale for moving etrasimod into alopecia areata and other dermatologic conditions. Etrasimod has demonstrated the potential to reduce circulating CD4+ and CD8+ T-lymphocytes. In alopecia areata, this may reduce the T cells available to infiltrate the hair follicle, which may decrease inflammation and restore hair growth. We expect the availability of Phase 2 data in 2021."

This Phase 2 multicenter, randomized, placebo-controlled trial will assess the safety and efficacy of once-daily etrasimod 2 mg in subjects with moderate-to-severe alopecia areata. The primary endpoint is percent change in Severity of Alopecia Tool (SALT) score from baseline to week 24. The trial will enroll 36 subjects and will be conducted in study sites across the United States and Canada.

About Alopecia Areata
Alopecia areata, or AA, is a T-cell-mediated autoimmune skin disorder with unmet medical need that causes non-scarring patchy hair loss, most often on the scalp. Mild disease typically presents as one or more round or oval bald patches on the scalp. In moderate-to-severe disease, extensive and chronic hair loss occurs, with the most severe forms involving hair loss on the entire scalp (alopecia totalis) or body (alopecia universalis). Patients with persistent moderate-to-severe AA also often suffer emotional and psychosocial distress and reduced quality of life as a result of their hair loss.

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 receptor 1, 4 and 5 which may lead to an improved efficacy and safety profile.

Etrasimod provides 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, 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 our 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 our medicines to patients, and relentlessly execute until it's done.

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," "potential," "will," "look forward to," "expect," and "may," and include, without limitation, statements about the following: the opportunity, development and potential of etrasimod, including regarding its design, its safety and efficacy, its therapeutic potential in immune-mediated inflammatory diseases such as ulcerative colitis, Crohn's disease, atopic dermatitis, and alopecia areata, and its ability to reduce patients' distress, improve lives, and satisfy an unmet medical or clinical need; the Phase 2 trial, including enrollment, study sites, trial design, and timing of Phase 2 data; the significance of the trial and its initiation; and Arena's purpose, work, understanding, ideas, and execution. 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 June 30, 2020, which was filed with the SEC on August 5, 2020. 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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