Aerie Pharmaceuticals Initiates Phase 2 Clinical Trial of AR-1105 (Dexamethasone Intravitreal Implant) in Patients with Macular Edema Associated with Retinal Vein Occlusion

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DURHAM, N.C.--(BUSINESS WIRE)--Mar. 18, 2019-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI) (Aerie), an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, retinal diseases and other diseases of the eye, today announced the commencement of patient dosing in a Phase 2 clinical trial of AR-1105, its investigational dexamethasone intravitreal implant, in patients with macular edema due to retinal vein occlusion (RVO).

This Phase 2 study (AR1105-CS201) will be conducted at approximately 20 centers in the United States and enroll up to 45 patients. The primary objectives of the trial are to evaluate the safety, tolerability and efficacy of the AR-1105 dexamethasone intravitreal implant. The study will be conducted in two stages. In the initial safety stage, up to 5 patients will be enrolled in a single cohort to receive clinical formulation #1 (CF-1), delivering a 340µg dose of dexamethasone in a single intravitreal injection. In Stage 2, up to 40 patients will be randomized 1:1 to receive either CF-1 or a second clinical formulation, CF-2, which delivers the same dose of dexamethasone over a longer period. Safety and efficacy will be evaluated at six months. More information about the study is available at www.clinicaltrials.gov under the study designation NCT 03739593.

“This is a proof of concept study for AR-1105 and for the retina portfolio we are building based on two enabling technologies, the bio-erodible polymers we are developing with DSM and our PRINT® manufacturing platform,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer. “The results of this trial should allow us to optimize the formulation of AR-1105 to achieve this clinical objective in Phase 3 studies. By the end of this quarter, we also plan to file an Investigational New Drug (IND) application for our second sustained delivery retina product, AR-13503 Implant, a bio-erodible implant delivering a Rho kinase/Protein kinase C inhibitor for the treatment of wet age-related macular degeneration and diabetic macular edema.”

About AR-1105

AR-1105 is a bio-erodible implant that is designed to steadily release the steroid dexamethasone over a six-month period. It is administered by intravitreal injection, a commonly-used, in-office treatment method. In addition to its six-month duration of effect, the potential benefits of AR-1105 compared to other intravitreal steroid products include improved administration with a smaller 25G needle and the potential for fewer adverse events due to lower peak drug levels. The market for retinal disease therapeutics in the United States, which is dominated by anti-VEGF agents, was approximately $6 billion in 2018. The intravitreal steroid segment represented approximately $200 million of that total.

About Aerie Pharmaceuticals, Inc.

Aerie is an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, retinal diseases and other diseases of the eye. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eyedrop approved by the U.S. Food and Drug Administration (FDA) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, was launched in the United States in April 2018. In clinical trials of Rhopressa®, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the product label, is available at www.rhopressa.com. Aerie’s second product for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, Rocklatan ™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, the first and only fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, has been approved by the FDA and is expected to be launched in the United States in the second quarter of 2019. In clinical trials of Rocklatan ™ the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan ™ including the product label, is available at www.rocklatan.com. Aerie continues to focus on global expansion and the development of additional product candidates and technologies in ophthalmology, including for wet age-related macular degeneration and diabetic macular edema. More information is available at www.aeriepharma.com.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “exploring,” “pursuing” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding the commercialization and manufacturing of Rhopressa® and Rocklatan™ or any future product candidates, including the timing, cost or other aspects of the commercial launch of Rhopressa® and Rocklatan™ or any future product candidates; our commercialization, marketing, manufacturing and supply management capabilities and strategies; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa® and Rocklatan™, with respect to regulatory approval outside of the United States or additional indications, and any future product candidates, including statements regarding

the timing of initiation and completion of the studies and trials; such as statements in this press release regarding any expected clinical trials for AR-1105 or AR-13503 and results of such clinical trials; the timing of and our ability to request, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, as applicable, Rhopressa®, Rocklatan™ or any future product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for, as applicable, Rhopressa®, Rocklatan™ or any future product candidates; the potential advantages of Rhopressa® and Rocklatan™ or any future product candidates; our plans to pursue development of additional product candidates and technologies within and beyond ophthalmology; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma, including development of our retina program; our ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, industry change and other factors beyond our control, and depend on regulatory approvals and economic and other environmental circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We discuss many of these risks in greater detail under the heading “Risk Factors” in the quarterly and annual reports that we file with the Securities and Exchange Commission (SEC). In particular, FDA approval of Rhopressa® and Rocklatan™ do not constitute FDA approval of AR-1105, AR-13503 or any future product candidates, and there can be no assurance that we will receive FDA approval for AR-1105, AR-13503 or any future product candidates. FDA approval of Rhopressa® and Rocklatan™ also do not constitute regulatory approval of Rhopressa® and Rocklatan™ in jurisdictions outside the United States and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan™ in jurisdictions outside the United States. Forward-looking statements are not guarantees of future performance and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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