Aerie Pharmaceuticals Initiates Phase 2b Clinical Trial of AR-15512 (TRPM8 Agonist) Ophthalmic Solution for the Treatment of Patients with Dry Eye Disease

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-First Patient Dosed in 90-Day Efficacy Trial Named COMET-1-

DURHAM, N.C.--(BUSINESS WIRE)--Oct. 29, 2020-- Aerie Pharmaceuticals, Inc. (NASDAQ: AERI), 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, ocular surface diseases and retinal diseases, today announced the commencement of COMET-1, a Phase 2b clinical trial of AR-15512 (TRPM8 agonist) ophthalmic solution for the treatment of patients with dry eye disease.

The COMET-1 trial is a randomized, double-masked, vehicle-controlled trial evaluating the efficacy and safety of AR-15512 (TRPM8 agonist) in patients with dry eye disease. Approximately 360 patients in total are expected to be enrolled. Patients will receive either AR-15512 0.0014%, AR-15512 0.003% or AR-15512 vehicle dosed as one drop twice daily in each eye over three months. The primary efficacy endpoints of the clinical trial are ocular discomfort (symptom) and tear production (sign). Patients will be evaluated on multiple efficacy assessments at days 14, 28 and 84; safety will be assessed at all visits. Topline results from COMET-1 are expected in the third quarter of 2021. More information about the clinical trial is available at www.clinicaltrials.gov under the study designation NCT04498182.

“We are excited to initiate COMET-1, Aerie’s first dry eye clinical trial,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. “With an estimated 30 million dry eye sufferers in the United States and less than 3 million treated, we believe there is a substantial unmet need in the treatment of dry eye disease. By activating the TRPM8 receptor, AR-15512 may stimulate tear production as well as reduce ocular discomfort through a mild cooling sensation. We anticipate topline results of COMET-1, which is powered as a Phase 3, in the third quarter of 2021.”

AR-15512, formerly AVX-012, was acquired by Aerie in November 2019 in the acquisition of Avizorex Pharma, S.L., a Spanish ophthalmic pharmaceutical company developing therapeutics for the treatment of dry eye disease.

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, ocular surface diseases and retinal diseases. Aerie’s first product, Rhopressa ® (netarsudil ophthalmic solution) 0.02%, a once-daily eye drop 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 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, was launched in the United States in May 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 in this release include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the duration and severity of the coronavirus disease (COVID-19) outbreak, including the impact on our clinical and commercial operations, demand for our products and financial results and condition of our global supply chains; our expectations regarding the commercialization and manufacturing of Rhopressa®, Rocklatan®, Rhokiinsa® and Roclanda® or any current or future product candidates, including the timing, cost or other aspects of their commercial launch; our commercialization, marketing, manufacturing and supply management capabilities and strategies in and outside of the United States; 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, and any current

or 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-15512 (formerly AVX-012), AR-1105 or AR-13503 and the results of such clinical trials; our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any current or future product candidates; 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 current or 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 current or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any current or future product candidates; our plans to pursue development of additional product candidates and technologies; 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. In particular, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of AR-15512, AR-1105 or AR-13503 or any future product candidates, and there can be no assurance that we will receive FDA approval for AR-15512, AR-1105 or AR-13503 or any future product candidates. In addition, the initiation of the clinical trial discussed in this press release does not constitute FDA approval of AR-15512 and the outcome of later clinical trials for AR-15512, including the clinical trial discussed in this press release, may not be sufficient to submit an NDA with the FDA or to receive FDA approval. 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). 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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