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

April 29, 2021

Topline results expected in the third quarter of 2021

DURHAM, N.C.--(BUSINESS WIRE)--Apr. 29, 2021-- 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 completion of patient enrollment for COMET-1, a Phase 2b clinical trial of AR-15512 (TRPM8 Agonist) ("AR-15512") ophthalmic solution for the treatment of patients with dry eye disease.

The first patient to enter this randomized, double-masked, vehicle-controlled Phase 2b clinical trial evaluating the efficacy and safety of AR-15512 in patients with dry eye disease was dosed in October 2020. A total of 369 patients were randomized across three arms, AR-15512 (0.0014%), AR-15512 (0.003%) or AR-15512 vehicle. Patients were given one drop twice daily in each eye over three months. Patients are evaluated at days 14, 28 and 84, with the primary efficacy measures of ocular discomfort (a symptom) and tear production (a sign). The regulatory pathway for dry eye product approval requires that both safety and efficacy need to be demonstrated in at least 2 well-controlled clinical trials. Efficacy for sign and symptom do not need to be shown in the same trial but both have to be shown in multiple trials. More information about the clinical trial is available at www.clinicaltrials.gov under the study designation NCT04498182.

"With an estimated 30 million dry eye sufferers in the United States and less than 3 million treated, there remains a significant unmet need in the treatment of dry eye disease. When activated, the TRPM8 receptor may increase tear production, a sign for dry eye disease, and its cooling sensation may lead to reduction in discomfort and ocular pain, a symptom of dry eye disease. This unique mechanism of action targeting both the signs and symptoms of dry eye disease is different from currently marketed eye products and we believe has the potential for use as a monotherapy and in conjunction with other approved products," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "We are pleased that our dry eye clinical activities continue to advance with the completion of enrollment in this Phase 2b clinical trial, COMET-1. We currently expect to report topline results for this trial in the third quarter of this year."

AR-15512, formerly AVX-012, was acquired by Aerie in November 2019 in connection with the acquisition of Avizorex Pharma, S.L., a Spanish ophthalmic pharmaceutical company developing therapeutics for the treatment of dry eye disease. AR-15512 has intellectual property protection for pharmaceutical composition and method of use through 2031.

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 product candidates, including AR-15512, or other 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 product candidates, including AR-15512, or future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any product candidates, including AR-15512, or other 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 product candidates, preclinical implants or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any product candidates 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 or to develop new intellectual property; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, FDA and European Medicines Agency (EMA) approval of Rhopressa® and Rocklatan® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions, including Japan's PMDA. In addition, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our product candidates, including AR-15512, or any future product candidates, and there can be no assurance that we will receive FDA approval for our product candidates or any future product candidates. 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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