Aerie Pharmaceuticals Completes Enrollment of the Netarsudil Ophthalmic Solution Phase 2 Clinical Trial in Japan Months Ahead of Schedule

July 9, 2019

DURHAM, N.C.--(BUSINESS WIRE)--Jul. 9, 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 that enrollment for its Phase 2 clinical trial of netarsudil ophthalmic solution in Japan is complete, a milestone reached several months earlier than previously anticipated.

The first patients to enter this prospective, double-masked, multi-center, placebo-controlled, parallel group Phase 2 study were dosed in late March 2019. In approximately 3 months, a total of 215 patients were successfully randomized across four treatment arms: netarsudil ophthalmic solution 0.01%, netarsudil ophthalmic solution 0.02%, netarsudil ophthalmic solution 0.04%, and placebo, all administered once daily in the evening. Netarsudil ophthalmic solution 0.02% is known by the name Rhopressa® in the United States where it is approved for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

“We believe this rapid enrollment reflects the enthusiasm of the clinical investigators at the 25 centers across Japan that participated in the study and is a credit to our clinical operations teams in Tokyo and the United States,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. “We expect to have topline data from this study in fourth-quarter 2019, allowing us to confirm the concentration of netarsudil we will take forward into Phase 3 trials in Japan.”

The study was designed in accordance with the requirements of Japan’s PMDA (Pharmaceuticals and Medical Devices Agency) as a precursor to Phase 3 trials supporting potential regulatory submission of netarsudil ophthalmic solution in Japan. The objective of the study is to evaluate the IOP-reducing effect and safety of the three concentrations of netarsudil ophthalmic solution over a 28-day period. Entry criteria include unmedicated baseline IOP ranges at 9:00 AM of 15 mmHg (millimeters of mercury) to less than 35 mmHg for patients with open-angle glaucoma, and 22 mmHg to less than 35 mmHg for patients with ocular hypertension. Studies of glaucoma in Japan suggest that patients have baseline IOP that is generally lower than patients in other populations, hence the baseline IOP range in this study begins at 15 mmHg, lower than is typical of glaucoma studies in the United States or Europe.

As agreed with the PMDA, the design of this trial is consistent with that of a recent Phase 2 pilot study that Aerie conducted in a Japanese-American population in the United States, with the addition of the netarsudil ophthalmic solution 0.01% treatment arm to confirm the concentration of netarsudil most suitable for Japanese patients. Topline results of the pilot study showed that netarsudil ophthalmic solution 0.02% reduced mean diurnal IOP by a range of 5.0 to 5.3 mmHg in patients with an average baseline IOP of 18.3 mmHg and netarsudil ophthalmic solution 0.04% reduced mean diurnal IOP by a range of 5.2 to 6.6 mmHg in patients with average baseline IOP of 20.2 mmHg. Both netarsudil arms produced significantly greater IOP reduction than placebo at Day 28. The safety findings were consistent with previous netarsudil trials.

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 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, has been approved by the FDA and was 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. In this release those include discussion of our expectations regarding the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials in Japan, and the expected timing of, and timing of regulatory and/or other review of, filings for, as applicable, netarsudil ophthalmic solution and any future product candidates and technologies within and beyond ophthalmology. 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 any future product candidates. FDA approval of Rhopressa® and Rocklatan® 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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