



## **Aerie Pharmaceuticals Initiates Netarsudil Ophthalmic Solution Phase 2 Clinical Trial in Japan Designed to Support Requirements for Future Regulatory Filing**

March 21, 2019

DURHAM, N.C.--(BUSINESS WIRE)--Mar. 21, 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 its Phase 2 clinical trial designed in accordance with the requirements of Japan's PMDA ( Pharmaceuticals and Medical Devices Agency) to support potential regulatory submission of netarsudil ophthalmic solution in Japan. Netarsudil ophthalmic solution 0.02% is known by the name Rhopressa® in the United States and is approved for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

This Phase 2 trial is being conducted in Japan as a precursor to Phase 3 registration trials in that country. The prospective, double-masked, multi-center, placebo-controlled, parallel group study is designed to evaluate the IOP-reducing effect and safety of 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. A total of approximately 208 patients will be randomized equally 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.

As agreed with the PMDA, the design of this trial is consistent with that of a recent Phase 2 pilot study 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 this population. Studies of glaucoma in Japan suggest that patients have baseline IOP that is generally lower than those experienced by patients in the United States and Europe, hence the IOP range in the netarsudil Japanese Phase 2 trials begins lower, at 15 mmHg.

"Building upon the positive topline results of our pilot Phase 2 study, we are very pleased to take this next step on the pathway toward a regulatory filing in Japan for netarsudil ophthalmic solution," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "We anticipate completing enrollment in this study before the end of 2019 and then preparing for a netarsudil Phase 3 program. We believe there continues to be substantial unmet need for novel glaucoma therapeutics in Japan, particularly medicines that are effective in patients with low baseline intraocular pressures."

Topline results of the Phase 2 pilot study in Japanese Americans were announced in January 2019. In that study, 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. 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 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](http://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](http://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](http://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; 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 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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