Aerie Pharmaceuticals Announces Positive Phase 3 Topline Results for Netarsudil Ophthalmic Solution 0.02% Clinical Trial in Japan

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Netarsudil Ophthalmic Solution 0.02% Once Daily Demonstrated Superiority to Ripasudil 0.4% Twice Daily

DURHAM, N.C.--(BUSINESS WIRE)--Oct. 12, 2021-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), an ophthalmic pharmaceutical company, today reported positive topline results for the Company's Phase 3 clinical trial in Japan evaluating netarsudil ophthalmic solution 0.02% ("netarsudil 0.02%") versus ripasudil hydrochloride hydrate ophthalmic solution 0.4% ("ripasudil 0.4%"). The results showed that netarsudil 0.02% once daily was superior to ripasudil 0.4% twice daily in lowering intraocular pressure ("IOP") at week four ($p<0.0001$), the primary endpoint for the study.

Both netarsudil 0.02% and ripasudil 0.4% are Rho kinase (ROCK) inhibitors. They are designed to treat open-angle glaucoma and elevated IOP by increasing outflow of aqueous humor through the trabecular outflow pathway, the drainage pathway responsible for maintaining normal IOP in the eye.

The clinical trial was a single-masked comparison of netarsudil 0.02% dosed once daily versus ripasudil 0.4% dosed twice daily in 245 subjects for four weeks. The baseline mean diurnal IOP was 20.5 and 20.8 millimeters of mercury ("mmHg") in the netarsudil 0.02% and ripasudil 0.4% arm, respectively. At four weeks, netarsudil 0.02% reduced mean diurnal IOP by 4.7 mmHg (22.6%) from baseline compared to 3.0 mmHg (14.3%) with ripasudil 0.4% ($p<0.0001$).

Netarsudil 0.02% is known by the name Rhopressa® in the United States and is approved for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension. Netarsudil 0.02% is known by the name Rhokiinsa® in the European Union, where it is approved for the reduction of elevated IOP in adult patients with primary open-angle glaucoma or ocular hypertension.

"We are pleased to have successfully completed our first Phase 3 clinical trial in Japan which further confirmed that netarsudil ophthalmic solution 0.02% achieves impressive IOP-lowering efficacy in a patient population with lower baseline pressures. We believe that the statistically superior IOP-lowering of netarsudil versus the comparator in our study may suggest a very bright future for our product in Japan, a market where the comparator product is the only rho-kinase inhibitor commercially available. The IOP-lowering with netarsudil was consistent with that seen in the previous Phase 2 study conducted in Japan as well as in our ROCKET and MERCURY studies conducted in the United States for Rhopressa® and Rocklatan®, respectively. With its once-daily dosing and strong safety profile, we believe that netarsudil will fulfill an unmet need for these patients with lower baseline IOPs," said Benjamin F. McGraw, III, Pharm.D., Interim Executive Chairman at Aerie.

"The findings also suggest that the IOP reduction may predict strong efficacy in normal or low-tension glaucoma patients," said David A. Hollander, M.D., MBA, Chief R&D Officer at Aerie. "These patients suffer damage to the optic nerve in spite of having IOPs in the normal range. Historically it has been challenging to achieve the IOP reductions needed to prevent vision loss in this patient population."

Netarsudil Ophthalmic Solution Phase 3 Clinical Trial Highlights

- This randomized, multi-center, parallel-group Phase 3 clinical trial was initiated in November 2020. The objective of the study was to evaluate the ocular hypotensive efficacy and safety of netarsudil 0.02% once daily compared to ripasudil 0.4% twice daily, over a four-week period in patients with open angle glaucoma or ocular hypertension.
- The study was designed in accordance with the requirements of Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") to support the potential regulatory submission of netarsudil ophthalmic solution in Japan. The primary efficacy endpoint was mean diurnal IOP at four weeks.
- A total of 245 randomized subjects were included, with 122 subjects in the netarsudil 0.02% arm and 123 subjects in the ripasudil 0.4% arm. A total of 238 patients (97%) completed the study.
- The baseline mean diurnal IOP was 20.5 and 20.8 mmHg in the netarsudil 0.02% and ripasudil 0.4% arm, respectively.
- At week four (primary endpoint), the mean diurnal IOP was statistically significantly lower (16.0 mmHg) in the netarsudil 0.02% group compared to the ripasudil 0.4% group (17.7 mmHg, $p<0.0001$).

- Netarsudil 0.02% reduced mean diurnal IOP by 4.7 mmHg (22.6%) from baseline compared to 3.0 mmHg (14.3%) with ripasudil 0.4% (p<0.0001). Statistically significant IOP lowering with netarsudil was also observed at each of the study timepoints, 9 am, 11 am, and 4 pm at all study visits at weeks one, two and four (p<0.01).

- The medications were safe and well-tolerated. The most common treatment emergent adverse event was conjunctival hyperemia (54.9% of subjects with netarsudil 0.02% and 62.6% of subjects with ripasudil 0.4%). The majority of ocular adverse events were rated as mild.

Aerie and Santen Pharmaceutical Co., Ltd. (“Santen”) announced an exclusive collaboration and license agreement for Rhopressa ® and Rocklatan® (netarsudil and latanoprost ophthalmic solution 0.02%/0.0005%) in Japan and several other Asian countries in October 2020. As part of this agreement, Santen is responsible for all regulatory process and commercialization related to the products in the territories covered by the agreement; however, Aerie and Santen collaborated on this first Phase 3 clinical trial for Rhopressa® in Japan, which they co-funded.

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 the treatment of dry eye disease, 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, preclinical implants or other future product candidates, including the success of any partnerships or collaborations entered in connection therewith, and 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, preclinical implants 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, preclinical implants 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, preclinical implants 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, preclinical implants or any future product candidates, and there can be no assurance that we will receive FDA approval for our product candidates, preclinical implants 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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