Aerie Pharmaceuticals Submits Marketing Authorisation Application for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% in Europe

December 3, 2019

DURHAM, N.C.--(BUSINESS WIRE)--Dec. 3, 2019-- 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, retinal diseases and other diseases of the eye today announced that it has submitted the marketing authorisation application (MAA) for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% with the European Medicines Agency (EMA). Should the MAA for Roclanda® be accepted for review by the EMA, an opinion from the Committee for Medicinal Products for Human Use is expected in approximately 12 months. Roclanda® is currently marketed in the United States as Rocklatan®.

The MAA submission for Roclanda® was predicated on the receipt of a marketing authorisation for Rhokiinsa® (netarsudil ophthalmic solution) 0.02%, which the European Commission granted in November 2019. Rhokiinsa® is marketed as Rhopressa® in the United States.

“Our regulatory team and other internal support groups worked tirelessly to complete the Roclanda ® MAA filing so quickly after the receipt of the Rhokiinsa® marketing authorisation,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. “In Europe, fixed-dose combinations with prostaglandins are frequently prescribed for the reduction of intraocular pressure associated with glaucoma. If approved, the combination of our Rho kinase inhibitor with a prostaglandin would be a first for Europe, and we look forward to working with the EMA in the coming months with the goal of bringing this potential new treatment to patients. As EMA review of the Roclanda® MAA begins, we will be completing and analyzing our Mercury 3 study, which compares Roclanda® to the leading fixed-dose combination product in the European Union. We expect results from this study will be reported next year, which should support our pricing and reimbursement activities.”

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, was 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 concerning, among other things: our expectations regarding the commercialization and manufacturing of, as applicable, Rhopressa®, Rocklatan®, Rhokiinsa®, 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 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 or additional indications, and any current 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® 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®, Rhokiinsa®, Roclanda® 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 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. In particular, FDA approval of Rhopressa® and Rocklatan® and EMA approval of Rhokiinsa® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, including EMA approval of Roclanda®, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions, including EMA approval of Roclanda®. 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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