



Aerie Pharmaceuticals Receives Positive CHMP Opinion for Roclanda® in the European Union

November 13, 2020

-European Commission Decision Anticipated in Approximately Two Months-

DURHAM, N.C.--(BUSINESS WIRE)--Nov. 13, 2020-- 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 European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending approval of the marketing authorisation application (MAA) for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%. The recommended indication is the reduction of elevated intraocular pressure in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction.

The CHMP positive opinion is a scientific recommendation for marketing authorisation, which is referred to the European Commission for a final decision on the Company's MAA. The final decision is expected in approximately two months and will be applicable to all European Union member states plus Iceland, Norway and Liechtenstein.

"We are delighted that the CHMP has adopted a positive opinion for Roclanda®," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "We look forward to the European Commission's final decision on the MAA for Roclanda®, which is expected by early next year."

Roclanda® is currently marketed as Rocklatan® in the United States and is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or hypertension.

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 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 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 current or future product candidates; our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® 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[®] 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; 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[®] do not constitute FDA approval of any future product candidates, and there can be no assurance that we will receive FDA approval for any future product candidates. In addition, 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[®]. Furthermore, EMA acceptance of the MAA for Roclanda[®] and the CHMP opinion of Roclanda[®] do not constitute EMA approval of Roclanda[®], and there can be no assurance that we will receive 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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