



Aerie Pharmaceuticals Receives Marketing Authorisation of Roclanda® 50 micrograms/ml + 200 micrograms/ml Eye Drops, Solution (latanoprost + netarsudil) in Great Britain

April 19, 2021

DURHAM, N.C.--(BUSINESS WIRE)--Apr. 19, 2021-- 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 that Roclanda® 50 micrograms/ml + 200 micrograms/ml Eye Drops, Solution (latanoprost + netarsudil) ("Roclanda®") has received marketing authorisation from the Medicines and Healthcare Products Regulatory Agency ("MHRA") in Great Britain. Roclanda® is indicated for the reduction of elevated intraocular pressure ("IOP") in adult patients with primary open-angle glaucoma or ocular hypertension for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction (*reference [Great Britain Summary of Product Characteristics](#)*).

Roclanda® was granted a marketing authorisation by the European Commission ("EC") in January 2021 for the same indication. The EC marketing authorisation is valid in all 27 countries of the European Union, plus Iceland, Norway and Liechtenstein. Through the EC marketing authorisation, Roclanda® is also authorised in Northern Ireland. As the EC decision was received after the end of the Brexit transition period, Aerie was required to complete a further administrative step in order to obtain authorisation in Great Britain, which has now been granted.

"The authorisation of Roclanda® in Great Britain, the only fixed-dose combination IOP-lowering therapy with a prostaglandin analogue that does not include a beta blocker, is another important regulatory milestone for Aerie on the heels of the receipt of the EC marketing authorisation for Roclanda® in January," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "We continue to evaluate our potential collaboration opportunities in Europe and this authorisation is another important step in furthering those discussions."

Roclanda® was authorised by the U.S. Food and Drug Administration in March 2019 under the trade name Rocklatan® for the reduction of elevated IOP in patients with open-angle glaucoma or ocular 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, and instillation site pain. 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 product candidates 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 authorisation outside of the United

States, and any product candidates 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 or future product candidates; the timing of and our ability to request, obtain and maintain FDA or other regulatory authority authorisation 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 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 authorisation of Rhopressa[®] and Rocklatan[®], European Medicines Agency (EMA) authorisation Rhokiinsa[®] and Roclanda[®] and MHRA authorisation of Roclanda[®] do not constitute regulatory authorisation of Rhopressa[®] and Rocklatan[®] in other jurisdictions, and there can be no assurance that we will receive regulatory authorisation for Rhopressa[®] and Rocklatan[®] in such other jurisdictions. In addition, FDA authorisation of Rhopressa[®] and Rocklatan[®] do not constitute FDA authorisation of our product candidates or any future product candidates, and there can be no assurance that we will receive FDA authorisation for our product candidates 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 authorisations 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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