Aerie Pharmaceuticals Receives European Commission Approval for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%

January 11, 2021

DURHAM, N.C.--(BUSINESS WIRE)--Jan. 11, 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 the European Commission (EC) has granted a marketing authorisation for Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% for 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 marketing authorisation application (MAA) for Roclanda® was accepted for review by the European Medicines Agency (EMA) in January 2020. Aerie received a positive scientific opinion recommending approval of the Roclanda® MAA from the EMA's Committee for Medicinal Products for Human Use (CHMP) in November 2020.

"The receipt of the EC marketing authorisation for Roclanda®, which is the only fixed-dose combination IOP-lowering therapy with a prostaglandin analogue that does not include a beta blocker, is an important regulatory milestone for Aerie on the heels of the recently reported successful interim topline data from our Mercury 3 clinical trial which demonstrated efficacy that was non-inferior to Ganfort®," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "We are preparing for pricing discussions in Germany while continuing our evaluation of collaboration opportunities for Europe, and the receipt of this marketing authorisation represents an important step in furthering all of those discussions."

Roclanda® was approved by the U.S. Food and Drug Administration (FDA) in March 2019 under the trade name Rocklatan® for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Rhokiinsa® was granted a marketing authorisation by the EC in November 2019 for the reduction of elevated intraocular pressure in adult patients with primary open-angle glaucoma or ocular hypertension. Rhokiinsa® was approved by the FDA in December 2017 under the trade name Rhopressa® for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

The marketing authorisation is valid in all 27 countries of the European Union, plus Iceland, Norway and Liechtenstein. As the EC decision was received after the end of the Brexit transition period, Aerie will complete a further administrative step in order to obtain a license in the United Kingdom. No reexamination of clinical data by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) is expected.

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 current or future product candidates, and there can be no assurance that we will receive FDA approval for any current or future product candidates. In addition, FDA approval of Rhopressa® and Rocklatan® and the EC grant of a marketing authorisation for Rhokiinsa® and Roclanda® 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. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210111005071/en/

Media: Tad Heitmann 949-526-8747; theitmann@aeriepharma.com
Investors: Ami Bavishi 908-947-3949; abavishi@aeriepharma.com

Source: Aerie Pharmaceuticals, Inc.