



Aerie Pharmaceuticals Announces U.S. Food and Drug Administration Approval of its Athlone, Ireland Facility for Production of Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%

January 21, 2020

DURHAM, N.C.--(BUSINESS WIRE)--Jan. 21, 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, dry eye, retinal diseases and other diseases of the eye today announced that its sterile fill production facility in Athlone, Ireland has received approval from U.S. Food and Drug Administration (FDA) to produce Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% for the U.S. market. The regulatory clearance of the plant follows a successful preapproval inspection of the facility and FDA review of the New Drug Application Prior Approval Supplement (PAS), which added the Athlone production facility as a drug product manufacturer for Rocklatan®.

"I want to personally thank each and every employee for a job very well done. This is a very proud moment for our company, the culmination of a dream we first had in 2015 to better control our own destiny from a manufacturing standpoint," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "It is certainly not every day that a new, state-of-the-art pharmaceutical production facility comes on line, a career-high achievement for every member of the Athlone team and the Aerie departments that supported their work. Their accomplishment is even more remarkable because of the project's highly accelerated timeline. Design and construction of this facility was only initiated in 2017, in an empty building shell, but by early 2019 the facility had successfully completed Rocklatan® process validation batches, enabling our PAS to be submitted with the FDA in September. We aim to have Rhopressa® produced in Athlone later in 2020, and eventually, we anticipate that Athlone will supply our ophthalmic products for all the markets in which we will operate."

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, dry eye, 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 dry eye, 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 or 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, statements in this press release regarding our Athlone, Ireland facility are forward looking statements. 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[®] does not constitute regulatory approval of Roclanda[®] by the EMA, and there can be no assurance that we will receive regulatory approval of Roclanda[®] by the EMA. 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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