Aerie Pharmaceuticals Submits Prior Approval Supplement to the U.S. Food and Drug Administration to Allow Production of Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% in its Athlone Ireland Facility

September 19, 2019

DURHAM, N.C.--(BUSINESS WIRE)--Sep. 19, 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 the submission of a prior approval supplement (PAS) to the U.S. Food and Drug Administration (FDA). If approved, the PAS will permit production of Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% for sale in the United States in Aerie's new manufacturing plant in Athlone, Ireland.

"Along with the successful GMP inspection and authorization of the Athlone plant for product manufacturing by Ireland's Health Products Regulatory Authority (HPRA), we have also successfully executed process validation studies for Rocklatan® and generated stability data to support registration of the Athlone plant with the FDA," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer. "Our PAS submission is another milestone for Aerie as we continue to move towards having our state-of-the-art plant facilitate the global supply of Aerie products."

Based on FDA timelines, Aerie expects the PAS filing review to be completed within 60 days, with final PAS review in 4 months. In addition, the Company anticipates a preapproval inspection of the Athlone manufacturing plant during the 4-month review. A successful inspection along with FDA approval of the supplement would allow Rocklatan® to be manufactured in Athlone for sale in the United States in the first half of 2020. The Company also plans to file a PAS in the first half of 2020 to obtain FDA approval to manufacture Rhopressa® (netarsudil ophthalmic solution) 0.02% in Athlone.

Rocklatan® was approved by the FDA in the United States on March 12, 2019 and the commercial launch in the United States occurred on May 1, 2019.

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, has been 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 Rhopressa® and Rocklatan® or any current or future product candidates, including the timing, cost or other aspects of the commercial launch of Rhopressa® and Rocklatan® or any current or future product candidates; our commercialization, marketing, manufacturing and supply management capabilities and strategies; 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® 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® do not constitute permission to manufacture Rhopressa® and Rocklatan® by us and there can be no assurance that we will receive permission to manufacture Rhopressa® and Rocklatan®. 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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