



Aerie Pharmaceuticals, Inc. Announces Drug Application for Regulatory Approval Accepted for Review in Europe

October 9, 2018

European Medicines Agency (EMA) will begin review of the Marketing Authorisation Application (MAA) for Rhokiinsa® (netarsudil ophthalmic solution) 0.02%, currently marketed as Rhopressa® in the United States

DURHAM, N.C.--(BUSINESS WIRE)--Oct. 9, 2018-- 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, retina diseases and other diseases of the eye, today reported that the EMA has accepted for review the MAA for Rhokiinsa® (netarsudil ophthalmic solution) 0.02%. Rhokiinsa® is currently marketed as Rhopressa® in the United States and is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. An opinion from the EMA's Committee for Medicinal Products for Human Use on the MAA for Rhokiinsa® is expected in the second half of 2019.

"We are delighted that the European regulatory authorities have accepted our Rhokiinsa® filing for review. If Rhokiinsa® is approved, we plan to submit an MAA for Roclatan™ shortly thereafter," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "Our Mercury 3 Phase 3 trial for Roclatan™, Aerie's fixed-dose combination of Rhopressa® and latanoprost, is ongoing in several European countries, and we continue to expand our presence in Europe with nearly 60 employees on board. In addition to our manufacturing facility in Ireland, we are building our clinical, medical affairs and commercial teams in the European region. Additionally, we were well-represented at the recent 36th Congress of the European Society of Cataract and Refractive Surgeons in Vienna, including an active booth and our presentations and panel participation at the Ophthalmology Futures Forums."

Dr. Anido continued, "Separately, our plans remain on schedule for the initiation of our Phase 2 clinical trial for Rhopressa® in Japan early next year, including the opening of an Aerie office in Tokyo."

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, retina diseases and other diseases of the eye. Aerie's first product, Rhopressa®, a once-daily eyedrop 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, cornea verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the full product label, is available at www.rhopressa.com. Aerie's advanced-stage product candidate, Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, a fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, achieved its 3-month primary efficacy endpoint in two Phase 3 registration trials, Mercury 1 and Mercury 2, and also showed safety and efficacy throughout 12 months in Mercury 1. Aerie submitted the Roclatan™ New Drug Application (NDA) in May 2018 and, in July 2018, the FDA set the PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the Roclatan™ NDA for March 14, 2019. 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," "opportunities" 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 commercial launch and sales of Rhopressa® and Roclatan™ and Rhokiinsa® and any future product candidates, if approved; our commercialization, marketing, manufacturing and supply management capabilities and strategies; third-party payer coverage and reimbursement of Rhopressa®, Roclatan™ and Rhokiinsa® and any future product candidates, if approved; the glaucoma patient market size and the rate and degree of market adoption of Rhopressa®, Roclatan™ and Rhokiinsa® and any future product candidates, if approved, by eye-care professionals and patients; the timing cost or other aspects of the commercial launch of Rhopressa®, Roclatan™ and Rhokiinsa® and any future product candidates, if approved; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa® and/or Rhokiinsa®, with respect to regulatory approval outside the United States, and Roclatan™ and any future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our

expectations regarding the effectiveness of Rhopressa[®], Roclatan[™], Rhokiinsa[®] and any future product candidates and results of our clinical trials and any potential preclinical studies; 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[®], Roclatan[™], Rhokiinsa[®] and any future product candidates in the United States, Canada, Europe, Japan and elsewhere, including the expected timing of, and regulatory and/or other review of, filings for, as applicable, Rhopressa[®], Roclatan[™], Rhokiinsa[®] and any future product candidates; the potential advantages of Rhopressa[®], Roclatan[™], Rhokiinsa[®] and any future product candidates; our plans to pursue development of additional product candidates and technologies in ophthalmology, including development of Rhopressa[®], Roclatan[™] and Rhokiinsa[®] for additional indications, our preclinical retina programs and other therapeutic opportunities; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma and ophthalmology; our ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations regarding collaborations, licensing, acquisitions and strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. 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). In particular, FDA approval of Rhopressa[®] does not constitute FDA approval of Roclatan[™], and there can be no assurance that we will receive FDA approval for Roclatan[™] or for any future product candidates. FDA approval of Rhopressa[®] also does not constitute regulatory approval of Rhopressa[®] or Rhokiinsa[®] in jurisdictions outside the United States, and there can be no assurance that Rhopressa[®] or Rhokiinsa[®] will obtain regulatory approval in other jurisdictions.

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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