Aerie Pharmaceuticals Submits New Drug Application to U.S. Food and Drug Administration for RoclatanTM (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%

May 15, 2018

- Submitted as a 505(b)(2) with an Expected Ten-Month FDA Review -

DURHAM, N.C.--(BUSINESS WIRE)--May 15, 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 and other diseases of the eye, today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%. Roclatan™ is a once-daily eye drop designed to reduce intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. It is a fixed dose combination of Aerie's Rhopressa ®, which is currently available in the United States, and the widely-prescribed PGA (prostaglandin analog) latanoprost. Roclatan™ successfully achieved its primary efficacy endpoint in two Phase 3 registration trials, named Mercury 1 and Mercury 2, and also achieved successful 12-month safety and efficacy results in Mercury 1, the results of which are included in the NDA submission.

The expected FDA review period for Roclatan™ NDA is only ten months instead of twelve months because Aerie's submission is filed under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, since Roclatan™ is a fixed dose combination of two previously approved drugs in the United States.

"The Roclatan ™ NDA filing represents another significant achievement for Aerie this year, on top of our recent commercial launch of Rhopressa® in the United States. Since Roclatan™ is being filed through the 505(b)(2) regulatory pathway, in which both active ingredients, netarsudil and latanoprost, are already approved in the United States, we expect a ten-month FDA review. We believe, if approved, Roclatan™ has the potential to be the most efficacious therapy in the market for the reduction of IOP, which makes this submission all the more exciting for our valued employees, eye care professionals, and most importantly, patients who suffer from glaucoma or ocular hypertension," said Vicente Anido, Jr., Ph.D., Chief Executive Officer and Chairman at Aerie.

About Roclatan™

Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, is a once-daily eye drop designed to reduce intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. It is a fixed dose combination of Aerie's Rhopressa ®, which is currently available in the United States, and widely-prescribed PGA (prostaglandin analog) latanoprost. Roclatan™ successfully achieved its primary efficacy endpoint in two Phase 3 registration trials, named Mercury 1 and Mercury 2, and also achieved successful 12-month safety and efficacy results in Mercury 1, the results of which are included in the May 2018 NDA submission. A third Phase 3 trial for Roclatan™, named Mercury 3, is currently underway in Europe but is not required for approval in the United States.

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 and other diseases of the eye. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, was approved by the U.S. Food and Drug Administration (FDA) in December 2017 and was launched in the U.S. market in April 2018. A link to the full product label is available on the Aerie website at http://investors.aeriepharma.com. Aerie's advanced-stage product candidate, Roclatan ™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, which is a fixed dose combination of Rhopressa® and widely-prescribed PGA (prostaglandin analog) latanoprost, achieved its primary efficacy endpoint in two Phase 3 registration trials, named Mercury 1 and Mercury 2, and also achieved successful 12-month safety and efficacy results in Mercury 1. The Roclatan™ NDA submission took place in May 2018. Aerie is also focused on global expansion and the development of additional product candidates and technologies in ophthalmology.

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 commercial launch and sales of Rhopressa® and Roclatan™ 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® and Roclatan™ and any future product candidates, if approved; the glaucoma patient market size and the rate and degree of market adoption of Rhopressa® and Roclatan™ 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® and Roclatan™ and any future product candidates, if approved; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa®, 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™ 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™ 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™ and any future product candidates; the potential advantages of Rhopressa®,Roclatan™ and any future product candidates; our plans to pursue development of additional product candidates and technologies in ophthalmology, including development of Rhopressa® and Roclatan™ 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™ on the timeframe discussed in this press release, if at all, or for any future product candidates. FDA approval of Rhopressa® also does not constitute regulatory approval of Rhopressa® in jurisdictions outside the United States, and there can be no assurance that Rhopressa® 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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