Aerie Pharmaceuticals Announces Early Notification of FDA Acceptance of NDA Submission for Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% with PDUFA Date Set for March 14, 2019

July 23, 2018

DURHAM, N.C.--(BUSINESS WIRE)--Jul. 23, 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 it has received the "Day 74" notification from the U.S. Food and Drug Administration (FDA) earlier than scheduled, the FDA has completed its initial 60-day review of the NDA (new drug application) for Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% and the FDA has determined that the application is sufficiently complete to permit a substantive review. The PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the Roclatan™ NDA is set for March 14, 2019. This date reflects a standard 10-month review period and is consistent with management's expectations for the 505(b)(2) filing. The "Day 74" notification indicated that the FDA has not identified any potential review issues, and did not mention the need for an advisory committee.

"We are delighted with this positive news on our Roclatan™ NDA, and, if approved, we expect to be fully prepared to launch Roclatan™ using our existing sales force, which is already making excellent progress in the early months of our Rhopressa® launch," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer 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 ® (netarsudil ophthalmic solution) 0.02%, 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. Aerie submitted the Roclatan™ New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) 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. 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, retina diseases and other diseases of the eye. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, 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 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" 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20180723005106/en/

Source: Aerie Pharmaceuticals, Inc.

Aerie Pharmaceuticals
Media: Tad Heitmann, 949-526-8747; theitmann@aeriepharma.com
Investors: Richard Rubino, 908-947-3540; rrubino@aeriepharma.com
or
Burns McClellan, Inc., on behalf of Aerie Pharmaceuticals
Investors: Ami Bavishi, 212-213-0006; abavishi@burnsmc.com