May 15, 2017

Aerie Pharmaceuticals Announces FDA Acceptance of NDA Submission for Rhopressa™ (netarsudil ophthalmic solution) 0.02%

Receives Notification from FDA of PDUFA Date for Rhopressa™

PDUFA Date Set for February 28, 2018

IRVINE, Calif.--(BUSINESS WIRE)-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye, today reported that it has received notification from the U.S. Food and Drug Administration (FDA) that the FDA has completed its initial 60-day review of the Rhopressa™ NDA (new drug application) and 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 Rhopressa™ NDA is set for February 28, 2018. This date reflects a standard 12-month review period and is consistent with management's expectations. The notification also indicated that the FDA has not identified any potential review issues, and that the FDA is currently planning to hold an advisory committee.

"We are obviously delighted with this positive news on our Rhopressa™ NDA. The February 28, 2018 PDUFA date and the advisory committee plans are consistent with our previously disclosed expectations. Further, we very much look forward to the upcoming Mercury 2 Phase 3 readout for Roclatan™, which remains on track for this quarter," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

About Rhopressa™

Rhopressa™ (netarsudil ophthalmic solution) 0.02%, is a novel eye drop that we believe, if approved, would become the only once-daily product available that, based on Aerie's preclinical and clinical studies, specifically targets the trabecular meshwork, the eye's primary fluid drain and the diseased tissue responsible for elevated intraocular pressure (IOP) in glaucoma. Preclinical and clinical studies have also demonstrated that Rhopressa™ lowers episcleral venous pressure, which contributes approximately half of IOP in healthy subjects. Further, based on Aerie's preclinical studies, Rhopressa™ may provide an additional mechanism that reduces fluid production in the eye and therefore lowers IOP. Biochemically, the active ingredient in Rhopressa™, netarsudil, has been shown in Aerie studies to inhibit both Rho Kinase (ROCK) and norepinephrine transporter (NET). Recent preclinical studies have also shown that Rhopressa™ may have disease-modifying properties, including an anti-fibrotic effect of netarsudil on trabecular meshwork cells and the potential to increase perfusion of the trabecular meshwork.

The results of two Phase 3 registration trials (Rocket 2 and Rocket 1) for Rhopressa™ were included in the NDA submission to the FDA in February 2017. There were two additional Phase 3 registration trials for Rhopressa™, named Rocket 3 and Rocket 4. Rocket 3 was a small 12-month safety-only study in Canada that was not necessary for the NDA submission and for which we have discontinued enrollment. Rocket 4, which was completed in April 2017, was designed to provide adequate six-month safety data for regulatory filing purposes in Europe, and was also not necessary for the NDA submission. The 90-day efficacy results from Rocket 4 and Mercury 1, the initial Phase 3 registration trial for Aerie product candidate Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, were also included in the Rhopressa™ NDA submission as supportive. The FDA has set the PDUFA goal date for the completion of the FDA's review of the Rhopressa™ NDA for February 28, 2018.

About Aerie Pharmaceuticals, Inc.

Aerie is a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye. Aerie's two current product candidates are once-daily intraocular pressure lowering therapies with novel mechanisms of action to treat patients with glaucoma or ocular hypertension. The NDA for Rhopressa™ (netarsudil ophthalmic solution) 0.02% was submitted to the FDA in February 2017, and, in May 2017, the FDA set the PDUFA goal date for the completion of the FDA's review of the Rhopressa™ NDA for February 28, 2018. Aerie's second product candidate, Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, which is a fixed dose combination of Rhopressa™ and widely prescribed PGA latanoprost, currently has two Phase 3 registration trials underway, named Mercury 1 and Mercury 2. If these trials are successful, a Roclatan™ NDA submission is expected to take place in late 2017 or early 2018. Aerie is also focused on 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: the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for our current and potential future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the clinical effectiveness of our product candidates and results of our clinical trials; the timing of and our ability to request, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including the expected timing of, and timing of the FDA's review of, NDA filings for our product candidates; our expectations regarding the commercialization and manufacturing of our product candidates; the potential advantages of our product candidates; our plans to pursue development of additional product candidates and technologies in ophthalmology, including development of our product candidates for additional indications and other therapeutic opportunities; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma; 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 or product candidates or technologies. In particular, the receipt of the PDUFA date notification, the subject of this press release, does not constitute FDA acceptance of the Rhopressa™ NDA, and there can be no assurance that the FDA will complete its review by the PDUFA goal date, that the FDA will not require changes or additional data, whether as a result of recommendations, if any, made by the FDA advisory committee discussed in this press release or otherwise, that must be made or received before it will approve the NDA, if ever, or that the FDA will approve the NDA. In addition, the preclinical research discussed in this press release is preliminary and the outcome of such preclinical studies may not be predictive of the outcome of later clinical trials. Any future clinical trial results may not demonstrate safety and efficacy sufficient to obtain regulatory approval related to the preclinical research findings discussed in this press release. 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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