December 23, 2016

Aerie Pharmaceuticals Provides Update on Timing of NDA Filing for RhopressaTM (netarsudil ophthalmic solution) 0.02%

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 glaucoma and other diseases of the eye, today reported that it has been notified by its third party manufacturing vendor that the manufacturing line related to Rhopressa™ in their Tampa, Florida facility will not be ready for pre-approval inspection by the FDA until the end of February 2017. In October 2016, the Rhopressa™ NDA (New Drug Application) was withdrawn due to the contract drug product manufacturer not being prepared for pre-approval inspection by the FDA. The contract drug product manufacturer had previously advised Aerie and the FDA that it expected to be prepared for FDA inspection in January 2017. The delay apparently does not result from any new findings, but rather additional time needed to complete validation of new equipment.

Aerie now expects to resubmit the Rhopressa™ NDA filing near the end of the first quarter of 2017 after receiving notification from the contract drug product manufacturer that the manufacturing line related to Rhopressa™ at the Tampa, Florida site is inspection ready.

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 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 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™ provides an additional mechanism that reduces fluid production in the eye and therefore lowers IOP. Biochemically, Rhopressa™ 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 on the trabecular meshwork and the potential to increase perfusion of the trabecular meshwork. Preclinical research is also currently underway to evaluate the potential neuroprotective benefits of Rhopressa™.

The results of two Phase 3 registration trials (Rocket 2 and Rocket 1) for Rhopressa™ were included in a NDA filing submitted to the FDA in the third quarter of 2016 that was withdrawn in October 2016 due to the contract drug product manufacturer not being prepared for pre-approval inspection by the FDA, and is now expected to be resubmitted near the end of the first quarter of 2017. Rocket 2 will represent the pivotal trial, and Rocket 1 will be supportive. There are two additional Phase 3 registration trials currently underway for Rhopressa™, named Rocket 3 and Rocket 4. Rocket 3 is a 12-month safety-only study in Canada that is not needed for the NDA filing. Rocket 4 is designed to provide adequate six-month safety data for regulatory filing purposes in Europe, and is also not needed for the NDA filing. Available data 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%, are expected to be included in the resubmitted Rhopressa™ NDA filing as supportive.

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 lead product candidates are once-daily IOP-lowering therapies with novel mechanisms of action to treat patients with glaucoma or ocular hypertension. The NDA filing for Rhopressa™ (netarsudil ophthalmic solution) 0.02% was originally submitted in the third quarter of 2016 and is expected to be resubmitted near the end of the first quarter of 2017. The 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 filing is expected to take place near year-end 2017. 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 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 U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates, including the expected resubmission of the NDA filing for Rhopressa™ discussed in this press release; our expectations regarding the commercialization of our product candidates; our expectations related to the use of proceeds from our equity and debt financings; our estimates regarding anticipated capital requirements and our needs for additional financing; the potential advantages of our product candidates; our plans to pursue 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; and our ability to protect our proprietary technology and enforce our intellectual property rights. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on regulatory approvals and economic 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, 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. 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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