



Aerie Pharmaceuticals Initiates Netarsudil Ophthalmic Solution Phase 2 Clinical Trial Designed to Meet Requirements of Regulatory Filing in Japan

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IRVINE, Calif.--(BUSINESS WIRE)--Nov. 16, 2017-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI) (Aerie or the Company), 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 announced the commencement of patient dosing in its Phase 2 clinical trial designed in accordance with the requirements of Japan's PMDA (Pharmaceuticals and Medical Devices Agency) for potential regulatory submission of netarsudil ophthalmic solution in Japan. Netarsudil ophthalmic solution 0.02% is known by the name Rhopressa™ in the United States, for which there is an FDA (U.S. Food and Drug Administration) PDUFA (Prescription Drug User Fee Act) goal date of February 28, 2018.

This Phase 2 study will be conducted in the United States, enrolling Japanese and Japanese-American subjects as a precursor to Phase 3 trials that are expected to be subsequently conducted in Japan. The primary objectives of this Phase 2 trial are to evaluate for (1) non-inferiority the ocular hypotensive activity of two different dose concentrations of netarsudil ophthalmic solution relative to placebo over a 28-day period, and (2) the ocular and systemic safety of netarsudil ophthalmic solution relative to placebo over that period. Baseline IOP (intraocular pressure) ranges in the trial are greater than or equal to 15 mmHg (millimeters of mercury) to less than 35 mmHg for subjects with open angle glaucoma, and greater than 22 mmHg to less than 35 mmHg for subjects with ocular hypertension. The study will include three arms of approximately 60 patients each: a netarsudil ophthalmic solution 0.02% arm, a netarsudil ophthalmic solution 0.04% arm, and a placebo arm, all taken once daily in the evening.

"Our global expansion strategy is now in full execution mode for both Japan and Europe, with the previously announced initiation of Mercury 3 in Europe. We are excited to commence our journey to potentially gain approval in Japan for netarsudil ophthalmic solution. Studies in Japan have shown that Japanese glaucoma patients experience IOPs that are generally lower than those experienced in the United States and Europe, hence the IOP ranges in this study start at 15 mmHg. The Japanese glaucoma market is one of the largest in the world at approximately \$1 billion annually, and we believe there continues to be substantial unmet need in this market," 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 the Company believes, if approved, would become the only once-daily product available that, based on Aerie's preclinical and clinical studies to date, 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 (New Drug Application) 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 enrollment has been discontinued. Rocket 4, which was successfully 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 Prescription Drug User Fee Act (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 (New Drug Application) for Rhopressa™ (netarsudil ophthalmic solution) 0.02% was submitted to the U.S. Food and Drug Administration (FDA) in February 2017, and, in May 2017, the FDA set the PDUFA (Prescription Drug User Fee Act) 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, 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 is expected to take place in the second quarter of 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: 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 FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for our product candidates; our expectations regarding the commercialization of our product candidates; 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; 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. 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, the receipt of the PDUFA goal date notification and the FDA advisory committee’s vote in favor of Rhopressa™ do not constitute FDA approval 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 that must be made or received before it will approve the NDA, if ever, or that the FDA will approve the NDA. 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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