



aerie
pharmaceuticals, inc.

March 17, 2016

Aerie Pharmaceuticals Reports Update on Positive Safety Results for Rhopressa™ QD (netarsudil ophthalmic solution) 0.02%

Conference Call and Webcast with Accompanying Slides Today, March 17, at 5:00 p.m. ET

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 glaucoma therapies, today reported an update including further details on the safety profile for Rhopressa™ QD, a novel once-daily eye drop being tested for its ability to lower intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. The Company previously reported interim topline 12-month safety and efficacy data on February 17, 2016, for Aerie's second Phase 3 registration trial for Rhopressa™ QD, indicating that Rhopressa™ QD had a positive safety profile with sustained efficacy through the 12-month period. The Company expects to submit the NDA for Rhopressa™ QD in the third quarter of 2016. Management will host a conference call and provide accompanying slides to discuss this update at 5:00 p.m. ET today.

Rhopressa™ QD Safety Update Highlights

- | Detailed 90-day safety data from Rocket 1 and Rocket 2 for Rhopressa™ QD were shared with the FDA during the Pre-NDA meeting that was held in October of 2015.
- | Based on the Rhopressa™ QD safety and efficacy data reviewed by the Company to date, and in consideration of the adverse event and efficacy profiles of other products currently in the market, the Company believes that product candidate Rhopressa™ QD continues to have significant potential.
- | Patients with contraindications to timolol, or beta blockers in general, or otherwise presenting with cardiopulmonary issues, were excluded from both Rocket 1 and Rocket 2. Based on Centers for Disease Control and Prevention data from 2011 and 2014, an estimated 47% of the U.S. population older than 65 years of age has heart disease and chronic obstructive pulmonary disease, all of which are contraindications to timolol.^{1,2}
- | Since it is not systemically absorbed, Rhopressa™ QD has not shown any drug-related systemic effects, nor has it generated any serious adverse events. Every other product in the adjunctive market for glaucoma and ocular hypertension has a history of drug-related systemic effects. Rhopressa™ is being positioned to compete in the adjunctive market, which represents approximately half of the prescription volume for glaucoma products in the U.S.
- | The most prevalent adverse event for Rhopressa™ QD was conjunctival hyperemia, the large majority of which was considered mild. Fifty percent of Rhopressa™ QD patients experienced hyperemia at some point during the trial; however, only ten percent of the patients in the trial had hyperemia at each visit over the 12-month trial period.
- | Other adverse events for Rhopressa™ QD, including corneal deposits, conjunctival hemorrhages, blurry vision, and reduced visual acuity, all of which have been observed in safety data for other marketed products, were commonly sporadic or self-resolving for the 118 patients on Rhopressa™ QD for the 12-month period in Rocket 2.
- | Physicians' perspectives at the recent American Glaucoma Society Annual Meeting indicated a high level of interest in Rhopressa™ QD among glaucoma specialists due to its competitive efficacy, safety profile, once-daily dosing, adjunctive use with prostaglandins and novel mechanisms of action.
- | The slides posted to the Aerie website include an in-depth analysis, including images where applicable, of the Rhopressa™ QD adverse events noted in the safety data.

"Consistent with what we previously reported, Rhopressa™ QD continues to demonstrate a positive safety profile after our deeper dive into the safety data. We believe Rhopressa™, if approved, will be well-received by both ophthalmologists and the payer community. Our NDA filing remains on track for the third quarter of 2016," said Vicente Anido, Jr., Ph.D., Chief Executive Officer and Chairman at Aerie.

Dr. Anido continued, "When comparing the adverse event profile of Rhopressa™ to the other market-leading products, along with the durable efficacy profile and mechanisms of action, we remain very excited about the prospects for Rhopressa™ in the marketplace. The attributes of Rhopressa™ also confirm a very strong case for Roclatan™ which already showed a positive safety and efficacy profile in its Phase 2b trial."

Richard A. Lewis, M.D., Aerie's Chief Medical Officer and a glaucoma specialist, stated, "Having attended the American Glaucoma Society meeting two weeks ago, it is clear to me that the ophthalmologists in the glaucoma community see Rhopressa™ as an exciting new potential entrant in glaucoma therapy."

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 specifically targets the trabecular meshwork, the eye's primary fluid drain and the diseased tissue responsible for elevated IOP in glaucoma. Preclinical results have demonstrated that Rhopressa™ also lowers episcleral venous pressure, which contributes approximately half of IOP in healthy subjects. Further, Rhopressa™ provides an additional mechanism that reduces fluid production in the eye and therefore lowers IOP. Biochemically, Rhopressa™ is known to inhibit both Rho Kinase (ROCK) and norepinephrine transporter (NET). Recent preclinical studies have 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 representations above regarding the Rhopressa™ mechanisms of action are the result of Aerie's preclinical studies and clinical trials.

There are two Phase 3 registration trials (Rocket 2 and Rocket 1) for Rhopressa™ required for NDA filing. Rocket 2 will be the pivotal trial and Rocket 1 will be supportive for the NDA filing that we expect to submit to the FDA in the third quarter of 2016. Rocket 2, the interim safety results of which are discussed in this press release, is a 12-month trial which previously achieved its 90-day primary efficacy endpoint. For Rocket 2, the 90-day efficacy period included IOP measurements at week two, week six and day 90 at 8 am, 10 am and 4 pm. Thereafter, safety observations and IOP measurements were conducted at 8 am only at the end of months six, nine and twelve. Rocket 1, the results of which were initially reported in April 2015, was a 90-day efficacy trial that did not achieve its primary endpoint, but did achieve its pre-specified secondary endpoint. Rocket 3 is a 12-month safety-only study in Canada which is currently in progress but not needed for NDA filing. A fourth Phase 3 trial, Rocket 4, commenced in late September 2015, and is designed to provide adequate six-month safety data to meet regulatory filing requirements in Europe, and is also not required for the NDA filing in the U.S.

Conference Call / Web Cast Information

Aerie management will host a live conference call and webcast at 5:00 p.m. Eastern Time today to discuss an update to the Rhopressa™ Phase 3 twelve-month safety results from Rocket 2.

The live webcast and a replay may be accessed by visiting Aerie's website at <http://investors.aeriepharma.com>. In addition, key data slides from the Rocket 2 safety study will be discussed on the conference call and are posted to Aerie's website. Please connect to Aerie's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 1-888-734-0328 (U.S.) or 1-678-894-3054 (international) to listen to the live conference call. The conference ID number for the live call is 74114965. Please dial in approximately 10 minutes prior to the call. Telephone replay will be available approximately two hours after the call. To access the replay, please call 1-855-859-2056 (U.S.) or 1-404-537-3406 (international). The conference ID number for the replay is 74114965. The telephone replay will be available until March 24, 2016.

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 and ocular hypertension. It is expected that the NDA filing for Rhopressa™ (netarsudil ophthalmic solution) 0.02% will take place

in the third quarter of 2016. The second product candidate, RoclatanTM (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, which is a fixed dose combination of RhopressaTM and widely prescribed PGA latanoprost, currently has one Phase 3 registration trial underway, named Mercury 1, with a second trial expected to commence in March 2016. If these trials are successful, a RoclatanTM NDA filing is expected to take place in the second half of 2017. Aerie also announced in 2015 its research collaborations with GrayBug, Inc. and Ramot at Tel Aviv University as it further builds its pipeline for future growth.

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 obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; our expectations regarding the commercialization of our product candidates; our expectations related to the use of proceeds from our initial public offering and the issuance and sale of our senior secured convertible notes and the issuance and sale of shares of our common stock in connection with our "at the market" sales agreements; 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; 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. 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. In addition, the financial information presented above is preliminary, based solely on information available to us as of the date of this press release, and may differ materially from final 2015 financial results. 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.

¹ <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6146a2.htm>

² Summary Health Statistics: National Health Interview Survey, 2014

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