



April 12, 2017

## **Aerie Pharmaceuticals Reports Positive Rocket 4 Six-Month Topline Safety and Efficacy Results for Rhopressa™ (netarsudil ophthalmic solution) 0.02%**

**Conference Call and Webcast Today, April 12, 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 therapies for the treatment of glaucoma and other diseases of the eye, today reported the successful six-month topline safety and efficacy results of its Rocket 4 Phase 3 clinical trial for product candidate Rhopressa™, a novel once-daily eye drop being tested for its ability to lower intraocular pressure (IOP) in patients with glaucoma or ocular hypertension. The Rocket 4 trial was designed to provide six-month safety data adequate for European regulatory filing purposes. Rocket 4 was not necessary for U.S. NDA (New Drug Application) filing purposes, although data from the 90-day efficacy component of the trial was included in the February 2017 Rhopressa™ NDA submission as supportive.

Rocket 4 enrollment totaled approximately 700 patients and was a two-arm six-month trial, which included a 90-day efficacy readout evaluating once-daily Rhopressa™ for non-inferiority to twice-daily timolol. The 90-day efficacy readout, which took place in October 2016, demonstrated successful achievement of the 90-day primary efficacy endpoint. This final readout from Rocket 4 includes six-month safety data and diurnal efficacy measurements at months four, five and six, which do not constitute a primary efficacy endpoint.

Management will host a conference call and provide accompanying slides to discuss these results at 5:00 p.m. ET today.

### **Rhopressa™ Phase 3 Six-Month Topline Highlights for Rocket 4**

- | The objective of the Rhopressa™ Rocket 4 clinical trial is to provide six-month safety data adequate for regulatory filing in Europe and is not required for U.S. FDA approval. The European regulatory filing for Rhopressa™ is currently expected to take place in the second half of 2018.
- | Safety data observed over the six months were consistent with observations in previous Rhopressa™ three-month and twelve-month Phase 3 clinical trials.
- | The most common Rhopressa™ adverse event was hyperemia, or eye redness, which was reported in approximately 48 percent of patients, 75 percent of which was mild. Other adverse events, which have also been observed in previous Rhopressa™ clinical trials, were reported in 5 percent to 25 percent of patients, consistent with the 12-month safety data from Rocket 2. There were no drug-related systemic or serious adverse events.
- | Rhopressa™ performance at months four, five and six remained within the non-inferiority range compared to timolol at each of the intraocular pressure (IOP) measurement time points, including 8 a.m., 10 a.m., and 4 p.m. at baseline IOPs ranging from above 20 mmHg (millimeters of mercury) to below 25 mmHg, and also from above 20 mmHg to below 27 mmHg.
- | The Rocket 4 six-month efficacy results for Rhopressa™ demonstrated a consistent level of IOP lowering across all baseline IOPs in the trial, and consistent IOP lowering throughout the six-month period.

"These successful six-month Rocket 4 safety and efficacy results reconfirm, as observed in our previous clinical trials, that Rhopressa™ is an efficacious and well-tolerated drug. Rocket 4 represents the final Phase 3 clinical trial for Rhopressa™, and we now possess clinical data on Rhopressa™ for well over 2,000 patients," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

Dr. Anido continued, "We look forward to our upcoming 90-day efficacy readout later this quarter from Mercury 2, the second Phase 3 registration trial for Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%. Mercury 2 is structured consistently with Mercury 1, but is of 90-day duration. The 12-month safety data from Mercury 1 are expected in the third quarter of this year."

### **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. Rocket 2 represents the pivotal trial, and Rocket 1 is supportive. There were two recently completed 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 is now completed but was not necessary for the NDA submission. Rocket 4 was designed to provide adequate six-month safety data for regulatory filing purposes in Europe, and was also not needed 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.

### **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 the Rhopressa™ Phase 3 six-month clinical trial results from Rocket 4.

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 Rhopressa™ Rocket 4 study will be discussed on the conference call and are posted to the website. Please connect to the Company'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 4540190. 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 4540190. The telephone replay will be available until April 19, 2017.

### **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 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. 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 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 additional subsequent 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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