Aerie Pharmaceuticals Initiates Mercury 3 Clinical Trial of Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%

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First Patient Dosed in Clinical Trial Designed for European Market

IRVINE , Calif.--(BUSINESS WIRE)--Sep. 6, 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 Mercury 3, the Company's European Phase 3 clinical trial of Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, a novel once-daily eye drop that has successfully demonstrated in U.S. clinical trials its ability to lower intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Roclatan™ is a fixed dose combination of Aerie product candidate Rhopressa™ (netarsudil ophthalmic solution) 0.02% and latanoprost, the most widely prescribed PGA (prostaglandin analogue).

Mercury 3 has been designed to facilitate regulatory approval and commercialization in Europe and is not necessary for approval in the United States. As background, Aerie has completed all Phase 3 registration trial activity necessary for a Roclatan™ New Drug Application (NDA) filing with the U.S. Food and Drug Administration, which is expected to be submitted in the first half of 2018.

The Company estimates a total enrollment of approximately 500 patients in Mercury 3, a two-arm, six-month safety trial that also provides a 90-day interim efficacy readout comparing once-daily Roclatan™ for non-inferiority to Ganfort®, a widely prescribed fixed dose combination IOP-lowering therapy marketed in Europe, but not in the U.S. Each comparator arm will be dosed once daily in the evening. Patients will be evaluated with maximum baseline IOPs ranging from above 20 to below 36 mmHg (millimeters of mercury). The trial will be conducted primarily in the United Kingdom, France, Germany, Italy, Spain, and Belgium.

"This is the beginning of a new chapter for Aerie as we start our first Phase 3 clinical trial in Europe. We are pleased to have commenced Mercury 3 on schedule, and we currently expect to read out topline 90-day efficacy data for the trial by early 2019. As we continue to expand our global reach we also look forward to commencing our Rhopressa™ clinical program designed to address the Japanese market, scheduled to begin later in 2017," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

About Roclatan™

Roclatan™ is a once-daily eye drop that combines Rhopressa™, as described below, with latanoprost, a widely prescribed PGA. Based on the Company's preclinical studies and clinical trials to date, Aerie believes that Roclatan™, if approved, would be the first glaucoma product to lower IOP through all known mechanisms: (i) increasing fluid outflow through the trabecular meshwork, the eye's primary drain, (ii) increasing fluid outflow through the uveoscleral pathway, the eye's secondary drain, (iii) reducing fluid production in the eye, and (iv) reducing episcleral venous pressure (EVP). By covering the full spectrum of known IOP-lowering mechanisms, Roclatan™ has the potential to provide a greater IOP-lowering effect than any currently approved glaucoma product.

The first Phase 3 registration trial for Roclatan™, named Mercury 1, is a 12-month safety and efficacy trial, which was completed in July 2017. Mercury 1 had a successful 90- day efficacy readout in September 2016. The second Phase 3 registration trial, named Mercury 2, is a 90-day efficacy trial, which reported successful primary efficacy results in May 2017. The topline 90-day efficacy readouts for both Mercury 1 and Mercury 2 demonstrated that Roclatan™ was statistically superior to each of its components, thus achieving their primary clinical endpoints. Aerie expects to submit a Roclatan™ NDA to the U.S. Food and Drug Administration (FDA) in the first half of 2018. A third Phase 3 registration trial, named Mercury 3, has commenced in Europe and is the subject of this press release. Mercury 3 is not necessary for approval in the U.S., but rather to facilitate regulatory approval and commercialization in Europe.

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 first half of 2018. Aerie is also focused on international 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 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 regulatory and/or other review of, 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. 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 does 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, whether as a result of recommendations, if any, made by any FDA advisory committee 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. 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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Source: Aerie Pharmaceuticals, Inc.

Aerie Pharmaceuticals
Richard Rubino, 908-947-3540
rrubino@aeriepharma.com
or
Burns McClellan, Inc., on behalf of Aerie Pharmaceuticals
Investors
Ami Bavishi, 212-213-0006
abavishi@burnsmc.com
or
Media
Justin Jackson, 212-213-0006
jjackson@burnsmc.com