



Aerie Pharmaceuticals Announces U.S. FDA Approval of Rhopressa® (netarsudil ophthalmic solution) 0.02% for the Lowering of Elevated Intraocular Pressure in Patients with Open-Angle Glaucoma or Ocular Hypertension

December 18, 2017

Product Approved Ahead of the Scheduled PDUFA Date of February 28, 2018

IRVINE, Calif.--(BUSINESS WIRE)--Dec. 18, 2017-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI) (Aerie or the Company), an ophthalmic pharmaceutical company focused on the discovery, development, and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma and other diseases of the eye, today announced that the U.S. Food and Drug Administration (FDA) has approved Rhopressa® (netarsudil ophthalmic solution) 0.02% for the lowering of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. A link to the full product label is available on the Aerie website at <http://investors.aeriepharma.com>. The FDA approval decision was made two months ahead of the scheduled PDUFA (Prescription Drug User Fee Act) goal date of February 28, 2018.

"The approval of once-daily Rhopressa® represents the single greatest achievement in Aerie's history to date, and represents exciting news for patients with open-angle glaucoma or ocular hypertension, and physicians. It is a testament to years of successful research and development and the incredible talents of our dedicated employees, to whom we owe much gratitude. We have been preparing for commercialization for well over a year, and our plans are clear. We will hire our sales force of 100 sales representatives early in the first quarter of 2018, and plan to launch by mid-second quarter of 2018. As the 2018 year progresses, it is our goal to make strides in gaining formulary coverage for commercial plans, which represent approximately half of the U.S. market. The other half of the U.S. market is covered through Medicare Part D, and we expect our formulary presence for this market to commence in January 2019. We also remain on track to file our Roclatan™ new drug application to the FDA in second quarter 2018," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

Dr. Anido continued, "As we reflect on the Rhopressa® approval, we pay tribute to Aerie's late co-founder, Dr. David Epstein. He was a visionary in the field of glaucoma and always believed in the potential IOP-lowering benefits of Rho kinase inhibition. This is a fulfillment of his dream."

About Rhopressa®

Rhopressa® (netarsudil ophthalmic solution) 0.02%, is a novel once-daily eye drop for the lowering of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension, and was approved by the FDA in December 2017. Rhopressa® is believed to reduce IOP by increasing the outflow of aqueous humor (the fluid inside the eye) through the trabecular meshwork, the main fluid drain of the eye. A link to the full product label is available on the Aerie web site at <http://investors.aeriepharma.com>.

About Aerie Pharmaceuticals, Inc.

Aerie is an ophthalmic 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 first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, for the lowering of intraocular pressure (IOP) in patients with glaucoma or ocular hypertension, was approved by the U.S. Food and Drug Administration (FDA) in December 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, 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, FDA approval of Rhopressa® does not constitute approval of Roclatan™, and there can be no assurance that we will receive FDA approval for Roclatan™ or any future product candidates. 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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