Aerie Pharmaceuticals Announces Acceptance of Its Investigational New Drug Application for AR-1105 (Dexamethasone Intravitreal Implant)

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Phase 2 Clinical Study Initiating Later in First Quarter 2019

DURHAM, N.C.--(BUSINESS WIRE)--Jan. 17, 2019-- Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), 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, retina diseases and other diseases of the eye today announced that the U.S. Food and Drug Administration (FDA) has reviewed the Investigational New Drug Application (IND) for AR-1105 (dexamethasone intravitreal implant) and it is now in effect, allowing Aerie to initiate human studies in the treatment of macular edema due to retinal vein occlusion (RVO). The IND was submitted in December 2018. Aerie expects to initiate a Phase 2 clinical study later in the first quarter of 2019.

AR-1105 is a bio-erodible implant that is designed to release the steroid dexamethasone over a six-month sustained period. The method of administration is through commonly used intravitreal injection. The potential benefits of AR-1105 compared to other steroid products include six-month duration of efficacy, improved administration due to a smaller needle size, and possibly a better safety profile due to lower peak drug levels.

“AR-1105 is the first IND-stage treatment in Aerie’s retina pipeline, which is an important milestone for the company,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. “This quarter we also plan to file an IND for our second retina product, a bio-erodible implant containing the Rho kinase/Protein kinase C inhibitor AR-13503 that is being developed for wet age-related macular degeneration and diabetic macular edema. These products demonstrate the potential of our two enabling platforms for delivering drugs to the back of the eye, the bio-erodible polymer technology we licensed from DSM and the PRINT® manufacturing technology licensed from Envisia. As we advance these new treatments in our second significant therapeutic area in eye care, we continue to pursue our goal of building the next major ophthalmic pharmaceutical company.”

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 open-angle glaucoma, retina diseases and other diseases of the eye. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eyedrop approved by the U.S. Food and Drug Administration (FDA) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, was launched in the United States in April 2018. In clinical trials of Rhopressa®, the most common adverse reactions were conjunctival hyperemia, cornea verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the product label, is available at www.rhopressa.com. Aerie’s advanced-stage product candidate, Rocklatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, a fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, achieved its 3-month primary efficacy endpoint in two Phase 3 registration trials, Mercury 1 and Mercury 2, and also showed safety and efficacy throughout 12 months in Mercury 1. Aerie submitted the Rocklatan™ New Drug Application (NDA) in May 2018 and, in July 2018, the FDA set the PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA’s review of the Rocklatan™ NDA for March 14, 2019. Aerie continues to focus on global expansion and the development of additional product candidates and technologies in ophthalmology, including for wet age-related macular degeneration and diabetic macular edema. More information is available at www.aeriepharma.com.

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: our expectations regarding the commercialization and manufacturing of Rhopressa® and Rocklatan™ or any future product candidates, including the timing, cost or other aspects of the commercial launch of Rhopressa® and Rocklatan™ or any future product candidates; our commercialization, marketing, manufacturing and supply management capabilities and strategies; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa®, with respect to regulatory approval outside of the United States or additional indications, and Rocklatan™ or any future product candidates, including statements regarding the timing of initiation and completion of the studies and trials, such as statements in this press release regarding any expected clinical trials for AR-1105 or AR-13503 and results of such 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, as applicable, Rhopressa®, Rocklatan™ or any future product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for, as applicable, Rhopressa®, Rocklatan™ or any future product candidates; the potential advantages of Rhopressa® and Rocklatan™ or any future product candidates; our plans to pursue development of additional product candidates and

technologies within and beyond ophthalmology; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma, including development of our retina program; 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, 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 FDA approval of Rocklatan™, and there can be no assurance that we will receive FDA approval for Rocklatan™, AR-1105, AR-13503 or any future product candidates. FDA approval of Rhopressa® also does not constitute regulatory approval of Rhopressa® in jurisdictions outside the United States and there can be no assurance that we will receive regulatory approval for Rhopressa® in jurisdictions outside the United States. Our receipt of a Prescription Drug User Fee Act (PDUFA) goal date notification for Rocklatan™ does not constitute FDA approval of the Rocklatan™ New Drug Application (NDA), and there can be no assurance that the FDA will complete its review by the PDUFA goal date of March 14, 2019, 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. In addition, the acceptance of the IND discussed in this press release does not constitute FDA approval of AR-1105 and the outcome of later clinical trials for AR-1105 may not be sufficient to submit an NDA with the FDA or to receive FDA approval. 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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