Aerie Pharmaceuticals Announces Drug Delivery Asset Acquisition to Further Advance Its Retinal Disease Program

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IRVINE, Calif.--(BUSINESS WIRE)--Oct. 5, 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 that it has acquired from Envisia Therapeutics Inc. (Envisia) the rights to use PRINT® technology in ophthalmology and certain other assets. The PRINT® technology is a proprietary system capable of creating precisely engineered sustained release products utilizing fully-scalable manufacturing processes. Aerie intends to use this technology to accelerate the advancement of its pipeline to treat conditions in the back of the eye such as wet AMD (age-related macular degeneration) and diabetic retinopathy. Aerie's initial focus will be in using PRINT® to manufacture injectable implants containing its pre-clinical product candidate known as AR-13154, potentially in conjunction with the previously announced biodegradable polymer from DSM. In addition, Aerie acquired Envisia's intellectual property rights relating to ENV1105, Envisia's pre-clinical dexamethasone steroid product candidate for the treatment of diabetic macular edema (DME), which also utilizes the PRINT® technology.

Under the terms of the agreement, Envisia will receive an initial $25 million in the form of a combination of cash and Aerie common stock with the potential to earn additional payments subject to achievement of certain product approval milestones.

As previously announced, Aerie recently entered into a research collaboration agreement with DSM that includes an option to license DSM's bioerodible polymer implant technology. DSM's technology uses polyesteramide polymers to produce an injectable, thin fiber that is minute in size. Preclinical experiments have demonstrated early success in conjunction with AR-13154, including demonstration of linear, sustained elution rates over several months and achievement of target retinal drug concentrations. AR-13154 inhibits Rho kinase and Protein kinase C and thus can address vascular dysfunction, fibrosis, and inflammation. This molecule has generated lesion size decreases in a preclinical model of wet AMD at levels similar to the market-leading wet AMD anti-VEGF product, and has generated meaningful incremental lesion size reduction when added adjunctively to the anti-VEGF product. Preclinical studies also demonstrated the promising potential of this molecule to reduce neovascularization in a model of proliferative diabetic retinopathy.

"As we continue our IND-enabling activities for AR-13154, we are pleased to further enhance our drug delivery and manufacturing capabilities with the addition of the PRINT® platform. The PRINT® technology provides us with a flexible and scalable manufacturing platform to help facilitate our clinical trials for AR-13154, which we expect to initiate within the next 18 to 24 months, as well as access to pre-clinical product candidate ENV1105 for DME," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

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, acquire and develop additional ophthalmic products or product candidates or technologies, such as PRINT®. 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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