Aerie Pharmaceuticals Establishes GMP PRINT® Production Facility in an Expanded Global Headquarters

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The Company now occupies more than 60,000 sq. ft. of laboratory and office space at the Durham, North Carolina, facility

DURHAM, N.C.--(BUSINESS WIRE)--Oct. 23, 2018-- 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, retinal diseases and other diseases of the eye, today announced that it has built and commenced operation of its GMP (Good Manufacturing Practices)-validated manufacturing facility for production of ophthalmic implants using the proprietary PRINT® (Particle Replication in Non-wetting Templates) Technology platform. As a result of the compact footprint and efficiency of the PRINT® manufacturing process, the custom-designed 1,000 sq. ft. laboratory provides adequate capacity to produce all of the clinical product supply necessary for Aerie's two lead development programs focused on retinal diseases.

Aerie has also completed its expansion at the headquarters location in Durham, North Carolina, by occupying the entire building at 4301 Emperor Boulevard. The headquarters facility now comprises a total of more than 61,000 sq. ft. and houses nearly 70 employees, making it Aerie's largest office in the United States.

"In addition to focusing on the commercialization of our glaucoma franchise, we are actively engaged in building our pipeline, currently centered on our novel sustained release program being designed to address unmet needs in the treatment of retinal diseases," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "Our scientists and engineers in Durham continue to advance the pipeline by pairing our proprietary molecules with sustained-release, bio-erodible polymers to deliver the full value of the innovative PRINT® platform to our clinical program in retina, which we expect to initiate later in 2019."

Aerie acquired the rights to use PRINT® Technology in ophthalmology and certain other assets from Envisia Therapeutics in October 2017. Aerie is evaluating the use of PRINT® Technology to manufacture fully-biodegradable polymer implants capable of sustained delivery of drug therapy to the back of the eye. The Durham PRINT® GMP manufacturing laboratory will initially produce implants to support clinical trials of the AR-1105 (dexamethasone) implant and Aerie's proprietary Rho kinase/Protein kinase C inhibitor, AR-13503 implant. These implants are designed to allow twice-yearly injections for the treatment of sight-threatening retinal conditions including diabetic macular edema and neovascular age-related macular degeneration.

Aerie is also evaluating this technology platform for sustained release of therapies to the front of the eye, including to treat glaucoma or ocular hypertension, as examples.

About PRINT® Technology

Particle replication in non-wetting templates (PRINT®) is a proprietary, versatile manufacturing technology, based on processes developed in the semi-conductor and materials industries, that is used to engineer and produce precisely-sized and -shaped drug particles from the nanometer to millimeter size range with high batch-to-batch reproducibility and dose uniformity. It is compatible with a wide variety of drugs and excipients, including many classes of small molecules and biologics, and can be used in combination products with multiple active ingredients. For ocular drug delivery, PRINT® provides the ability to precisely manufacture small, injectable intraocular implants.

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, retinal 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, Roclatan™ (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 Roclatan™ 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 Roclatan ™ 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”, “opportunities” 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 of any development efforts growing out of Aerie’s collaboration with DSM for the treatment of macular degeneration or other ophthalmic uses, the likelihood that any such development efforts will result in product approval by the FDA or other Regulatory Agencies, our expectations regarding the commercial launch and sales of Rhopressa® and Roclatan™ and any future product candidates, if approved; our commercialization, marketing, manufacturing and supply management capabilities and strategies; third-party payer coverage and reimbursement of Rhopressa® and Roclatan™ and any future product candidates, if approved; the glaucoma patient market size and the rate and degree of market adoption of Rhopressa® and Roclatan™ and any future product candidates, if approved, by eye-care professionals and patients; the timing cost or other aspects of the commercial launch of Rhopressa® and Roclatan™ and any future product candidates, if approved; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa®, with respect to regulatory approval outside the United States, and Roclatan™ and any future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the effectiveness of Rhopressa®, Roclatan™ and any future product candidates and results of our clinical trials and any potential preclinical studies; 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®,Roclatan™ and any future product candidates in the United States, Canada, Europe, Japan and elsewhere, including the expected timing of, and regulatory and/or other review of, filings for, as applicable, Rhopressa®, Roclatan™ and any future product candidates; the potential advantages of Rhopressa®,Roclatan™ and any future product candidates; our plans to pursue development of additional product candidates and technologies in ophthalmology, including development of Rhopressa® and Roclatan™ for additional indications, our preclinical retina programs and other therapeutic opportunities; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma and ophthalmology; our ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations regarding collaborations, licensing, acquisitions and 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 Roclatan™, and there can be no assurance that we will receive FDA approval for Roclatan™ or for 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 Rhopressa® will obtain regulatory approval in other jurisdictions. 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
Media:
Tad Heitmann, 949-526-8747
theitmann@aeriepharma.com
or
Investors:
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