Aerie Concludes Exclusive License Agreement With Santen for Rhopressa® and Rocklatan® in Europe and Several Other Regions

December 7, 2021

Agreement includes Europe, Commonwealth of Independent States countries, China, India, parts of Latin America and the Oceania countries

DURHAM, N.C.--(BUSINESS WIRE)--Dec. 7, 2021-- Aerie Pharmaceuticals, Inc. (NASDAQ: AERI, “Aerie”) announced that Aerie and Santen have entered into an exclusive development and commercialization agreement for Rhopressa®/Rhokiinsa® (netarsudil ophthalmic solution) 0.02% and Rocklatan®/Roclanda® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%. The expanded collaboration includes Europe, Commonwealth of Independent States (CIS) countries, China, India, parts of Latin America and the Oceania countries.

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, ocular surface diseases and retinal diseases. Rhopressa® and Rocklatan® are approved and being sold in the United States by Aerie. Both Rhopressa® and Rocklatan® are also approved in Europe and known as Rhokiinsa® and Roclanda®, respectively.

“We are delighted to announce this development and commercialization agreement with Santen, a leading global ophthalmology company, which will extend the benefits of our unique products to patients with glaucoma or ocular hypertension in Europe and several other global regions. This is an expansion from our initial collaboration with Santen for Japan and East Asia, announced in October 2020, under which we have already successfully completed the first Phase 3 study for Rhopressa® in Japan. Additionally, Aerie will be manufacturing these products for Santen using our new manufacturing facility in Ireland. The ability to utilize this plant for global supply will have a positive impact to reduce the manufacturing cost of our own products in the United States. We have worked hard with Santen over this past year to expand our collaboration and we look forward to Santen bringing these products to more countries,” said Benjamin F. McGraw, III, Pharm.D., Interim Executive Chairman of the Board of Directors.

Under the terms of the agreement, Aerie will receive an upfront payment of $88 million, and various development, regulatory and sales milestones of up to $77 million. Aerie is also eligible to receive additional consideration in excess of 25% of the products’ net sales, such consideration consisting of the cost of products supplied to Santen from Aerie and a royalty for Aerie’s intellectual property. Santen will be responsible for sales, marketing and pricing decisions relating to the products. Santen will also be responsible for all development and commercialization costs and activities related to the products in the territories covered by the agreement with the exception of a post-marketing clinical study to be conducted by Aerie in Europe for Roclanda®. Aerie will be responsible for the manufacture and supply of the products to Santen utilizing its Athlone, Ireland plant. In addition to customary termination rights for both parties, in the event that patents are issued that may prevent the commercialization of the products in China, Santen would have the right to terminate the agreement for such country and require Aerie’s repayment of a portion of the upfront payment.

“With our cash and cash equivalents and investments of $168 million as of the end of the third quarter, the cash and milestones from this partnership put us in a very good financial position so that we have adequate resources to execute our business plan,” said Benjamin F. McGraw, III, Pharm.D.

About Glaucoma

Glaucoma is a disorder which causes optic nerve damage leading to visual field loss and is a major cause of visual impairment including decreased vision and blindness in many countries, especially in Japan and several other Asian countries. Since glaucomatous optic nerve damage and visual field defects are generally progressive and irreversible, early detection and treatment for controlling progression of damage is crucial in the treatment of glaucoma.

About Aerie

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, ocular surface diseases and retinal diseases. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eye drop 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, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the product label, is available at www.rhopressa.com. Aerie’s second product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, Rocklatan® (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, the first and only fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, was approved by the FDA and was launched in the United States in the second quarter of 2019. In clinical trials of Rocklatan®, the most common adverse reactions were

conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan®, including the product label, is available at www.rocklatan.com. Aerie continues to focus on global expansion and the development of additional product candidates and technologies in ophthalmology, including for the treatment of dry eye, wet age-related macular degeneration and diabetic macular edema. More information is available at www.aeriepharma.com.

Aerie 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 in this release include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the duration and severity of the coronavirus disease (COVID-19) outbreak, including the impact on our clinical and commercial operations, demand for our products, our financial results and condition of our global supply chains; our expectations regarding the commercialization and manufacturing of Rhopressa®, Rocklatan®, Rhokiinsa® and Roclanda® or any product candidates, preclinical implants or future product candidates, including the success of any partnerships or collaborations entered in connection therewith, including the collaboration and license agreement entered into with Santen, and the timing, cost or other aspects of their commercial launch; our commercialization, marketing, manufacturing and supply management capabilities and strategies in and outside of the United States; the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa® and Rocklatan®, with respect to regulatory approval outside of the United States, and any product candidates, preclinical implants or future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any product candidates, preclinical implants or future product candidates; 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 product candidates, preclinical implants or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any current or future product candidates; our plans to pursue development of additional product candidates and technologies; 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 or to develop new intellectual property; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, statements in this press release regarding our development and commercialization agreement with Santen, and payments related thereto, are forward-looking statements. In addition, FDA approval of Rhopressa® and Rocklatan® and EMA approval of Rhokiinsa® and Roclanda® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, including EMA approval of Rhokiinsa® and Roclanda®, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions. Additionally, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our product candidates, preclinical implants or future product candidates and there can be no assurance that we will receive FDA approval for our product candidates, preclinical implants or future product candidates. 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). 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.

About Santen

As a specialized company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products, and medical devices, and its products now reach patients in over 60 countries. Toward realizing “WORLD VISION” (Happiness with Vision), the world Santen ultimately aspires to achieve, as a “Social Innovator”, we aim to reduce the social and economic opportunity loss of people around the world caused by eye diseases and defects by orchestrating and mobilizing key technologies and players around the world. With scientific knowledge and organizational capabilities nurtured over a 130-year history, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society. For more information, please visit Santen’s website (www.santen.com).

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Aerie:

Media:
Carolyn McAuliffe
cmcauliffe@aeriepharma.com
(949) 526-8733

Investors:
LifeSci Advisors on behalf of Aerie Pharmaceuticals, Inc.
Hans Vitzthum
hans@lifesciadvisors.com
(617) 430-7578

Santen:

Takahiro Hidaka
Global Corporate Communications
Santen Pharmaceutical Co., Ltd.

Email: communication@Santen.com Tel: +81-6-7664-8621

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