Aerie Pharmaceuticals Reports Positive Topline Results for AR-1105 (Dexamethasone Intravitreal Implant) Phase 2 Clinical Trial in Patients with Macular Edema Due to Retinal Vein Occlusion

July 27, 2020

DURHAM, N.C.--(BUSINESS WIRE)--Jul. 27, 2020-- 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, ocular surface diseases and retinal diseases, today reported positive topline results for the Company's Phase 2 clinical trial evaluating AR-1105 (dexamethasone intravitreal implant) in patients with macular edema associated with retinal vein occlusion.

AR-1105 Phase 2 Highlights

- The Phase 2 clinical trial (AR-1105-CS201) was conducted at 19 centers in the United States. A total of 49 patients completed the study.
- The objective of the Phase 2 clinical trial was to evaluate two formulations of AR-1105, clinical formulation #1 (CF-1) and clinical formulation #2 (CF-2) with different steroid release profiles. The clinical trial was conducted in two stages. In the initial safety stage, five patients were enrolled in a single cohort to receive CF-1, delivering a 340µg dose of dexamethasone in a single intravitreal injection. In stage 2, 44 patients were randomized 1:1 to receive either CF-1 or CF-2.
- The results demonstrated positive and sustained treatment effects with both formulations as shown by increases in best corrected visual acuity and reductions in macular edema. Peak efficacy was observed earlier with CF-1, while CF-2 demonstrated a longer overall duration of effect of up to six months.
- Both formulations, CF-1 and CF-2, were well tolerated with no unexpected safety findings.
- Adverse events were consistent with other corticosteroid treatments and intravitreal injection procedures.
- Further details will be provided at an upcoming ophthalmology conference.

"The results of this study are very exciting. The formulation of AR-1105 appears to indicate that this therapy candidate may have the potential to deliver a long-acting treatment for patients with macular edema secondary to retinal vein occlusion," said Michael Singer, M.D., Director of Clinical Research at Medical Center Ophthalmology Associates and Clinical Professors of Ophthalmology at the University of Texas Health Science Center in San Antonio.

"We are very pleased with the AR-1105 clinical trial results, our first successful clinical trial from our retina program. The profiles of the different cohorts demonstrate the flexibility of our PRINT® sustained release technology platform in enhancing the management and durability of treatment effects. This product candidate would be a welcome addition to currently available steroid treatments with its potential for five to six months of sustained efficacy. Additionally, achieving up to six months of sustained efficacy is an important hurdle for Aerie as it would help validate the broad potential of our sustained release technology," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "As we have previously stated, we do not plan to initiate any new clinical trials for this product candidate until the second half of 2021, after we have seen the results of our other clinical trial programs, including our AR-13503 sustained release implant for wet age-related macular degeneration and diabetic macular edema, and AR-15512 for dry eye. In the interim, we plan to discuss the results with retina specialists as well as the regulatory agencies in both the United States and the European Union to determine the optimal path forward for AR-1105."

About AR-1105

The product candidate AR-1105 is a bio-erodible implant that, if approved, is designed to steadily release the steroid dexamethasone over a six-month period. It is administered by intravitreal injection, a commonly used, in-office treatment method. In addition to its duration of effect, AR-1105 offers the potential for a favorable safety profile based on peak drug levels. The market for retinal disease therapeutics totals nearly $7 billion in the United States and $4 billion in Europe.

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, 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 and 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 launched in the United States in May 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 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 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 and financial results and condition of our global supply chains; our expectations regarding the commercialization and manufacturing of Rhopressa®, Rocklatan®, Rhokiinsa® and Roclanda® or any current or future product candidates, including 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 current or 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-15512 (formerly AVX-012), AR-1105 or AR-13503 and the results of such clinical trials; our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any current 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 current or 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 current 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; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, the topline data presented herein is preliminary and based solely on information available to us as of the date of this press release and additional information about the results may be disclosed at any time. Additionally, FDA approval of Rhopressa® and Rocklatan® and EMA approval of Rhokiinsa® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, including EMA approval of Roclanda®, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions, including EMA approval of Roclanda®. In addition, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our current or any future product candidates, and there can be no assurance that we will receive FDA approval for our current or any future product candidates. Furthermore, EMA acceptance of the MAA for Roclanda® does not constitute EMA approval of Roclanda®, and there can be no assurance that we will receive EMA approval of Roclanda®. In addition, the acceptance of the INDs by the FDA for AR-15512, AR-1105 and AR-13503 do not constitute FDA approval of AR-15512, AR-1105 or AR-13503, respectively, and the outcomes of later clinical trials for AR-15512, AR-1105 or AR-13503 may not be sufficient to submit an NDA with the FDA or to receive FDA approval. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200727005023/en/

Media: Tad Heitmann 949-526-8747; theitmann@aeriepharma.com
Investors: Ami Bavishi 908-947-3949; abavishi@aeriepharma.com

Source: Aerie Pharmaceuticals, Inc.