



## **Aerie Pharmaceuticals Announces First Participant Dosed in the Phase 3 Registrational COMET-2 Study of AR-15512 for the Treatment of Dry Eye Disease**

May 24, 2022

*AR-15512 is a differentiated, novel, first-in-class product candidate for the treatment of the signs and symptoms of Dry Eye Disease*

*COMET-2 is the first of three studies in the AR-15512 Phase 3 Program*

DURHAM, N.C.--(BUSINESS WIRE)--May 24, 2022-- Aerie Pharmaceuticals, Inc. (NASDAQ: AERI), a pharmaceutical company focused on the discovery, development, and commercialization of first-in-class ophthalmic therapies, today announced that the **first participant has been dosed in the Phase 3 registrational "COMET-2" study to evaluate AR-15512 ophthalmic solution as a treatment for the signs and symptoms of dry eye disease (DED)**. COMET-2 is the first of three trials in the Phase 3 registrational program for AR-15512. Aerie plans to initiate the other two trials in the second half of 2022 in support of a potential New Drug Application (NDA) filing in 2024.

[COMET-2](#) is a randomized, double-masked, vehicle-controlled, multi-center clinical study to evaluate the efficacy and safety of AR-15512, a TRPM8 agonist, in patients with DED. The study is expected to enroll approximately 460 participants at 20 U.S. sites. Study participants will receive AR-15512 (0.003%) or AR-15512 vehicle as a drop dosed twice daily in each eye for three months. The primary efficacy assessment is tear production, as measured by the unanesthetized Schirmer test (sign), and the key secondary measure is dry eye symptoms based on the Symptom Assessment in Dry Eye (SANDE) questionnaire. Participants will be evaluated on multiple efficacy and safety assessments at multiple timepoints throughout the study. Topline results from the COMET-2 study are expected in the second half of 2023.

"Aerie is excited to mark the beginning of our registrational Phase 3 program for AR-15512 with the enrollment of the first participant in the COMET-2 study," said Michelle Senchyna, Ph.D., Head of Clinical Development and Medical Affairs at Aerie. "This study builds on the results of the COMET-1 study which showed statistically significant, dose-dependent improvements on multiple validated sign, symptom, and quality of life endpoints across multiple timepoints."

Dr. Senchyna continued, "There is a significant unmet need for an effective treatment that can provide a rapid and robust onset of efficacy, and meaningful relief of dry eye symptoms. AR-15512 has the potential to be the new standard of care for patients suffering from dry eye disease."

### **About the AR-15512 Phase 3 Registrational Program**

The AR-15512 Phase 3 registrational program is comprised of three studies, the COMET-2 and COMET-3 efficacy studies and the COMET-4 safety study, that will evaluate AR-15512 (0.003%) compared to AR-15512 vehicle in participants with DED. [COMET-2](#), which is currently enrolling, and [COMET-3](#), which is expected to begin in the third quarter of 2022, are identical studies with topline results expected in the second half of 2023. COMET-4, which is expected to begin in the fourth quarter of 2022, is a 12-month safety study. Aerie will incorporate interim 6-month data from COMET-4 into the NDA filing for AR-15512, which is expected to be submitted in 2024.

### **About AR-15512**

AR-15512 is a first-in-class TRPM8 agonist which acts as a cold thermoreceptor modulator to stimulate the cold sensing receptors found on the nerve endings that innervate the cornea and eyelids. By stimulating these receptors, AR-15512 leads to natural tear production and a cooling sensation across the surface of the eye that may result in a reduction in dry eye symptoms.

### **About Dry Eye Disease**

Dry eye disease affects about 30 million people in the U.S. It is estimated that about 60% of people with DED are diagnosed and less than 10% of patients are treated with prescription medications.<sup>1</sup> Current treatment is comprised of over-the-counter "artificial tears" and prescription anti-inflammatories and nasal tear stimulants.

### **About COMET-1**

The [COMET-1](#) study evaluated two doses of AR-15512 compared to AR-15512 vehicle in 369 participants with DED. As reported in September 2021, the trial did not achieve Aerie's previously chosen primary endpoints. The study showed a statistically significant, dose-dependent increase in tear production, a validated endpoint acceptable for registration of a product. In addition, AR-15512 demonstrated improvements on multiple validated sign, symptom, and quality of life endpoints across multiple timepoints. Importantly, the study showed that differences between AR-15512 and vehicle responses increased over time, indicating a potential sustained, meaningful treatment effect in DED signs and symptoms. COMET-1 demonstrated a favorable tolerability profile with no systemic or serious adverse events attributed to AR-15512.

*AR-15512 is a development stage product candidate and is not approved by any regulatory agency.*

### **About Aerie Pharmaceuticals, Inc.**

Aerie is a pharmaceutical company focused on the discovery, development, and commercialization of first-in-class ophthalmic therapies for the treatment of patients with eye diseases and conditions including open-angle glaucoma, dry eye, diabetic macular edema (DME), and wet age-related macular degeneration (wet AMD). Aerie's first novel product, Rhopressa<sup>®</sup> (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<sup>®</sup>, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa<sup>®</sup>, including the product label, is available at [www.rhopressa.com](http://www.rhopressa.com). Aerie's second novel product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, Rocklatan<sup>®</sup> (netarsudil (0.02%) and latanoprost ophthalmic solution (0.005%)), was launched in the United States in May 2019. In clinical trials of Rocklatan<sup>®</sup>, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan<sup>®</sup>, including the product label, is available at [www.rocklatan.com](http://www.rocklatan.com). More information on Aerie Pharmaceuticals is available at [www.aeriepharma.com](http://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 the 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, our commercial franchise and our pipeline, any guidance or timelines and our ongoing and anticipated preclinical studies and clinical trials, including Phase 3 trials for AR-15512. 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.

#### References:

1. Market Scope 2021 Dry Eye Product Market Review

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220524005496/en/): <https://www.businesswire.com/news/home/20220524005496/en/>

#### Media:

Carolyn McAuliffe  
[cmcauliffe@aeriepharma.com](mailto:cmcauliffe@aeriepharma.com)  
(949) 526-8733

#### Investors:

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

Source: Aerie Pharmaceuticals, Inc.