

# Orasis Pharmaceuticals Submits New Drug Application for Investigational Novel Eye Drop Candidate, CSF-1, for the Treatment of Presbyopia



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**Orasis Pharmaceuticals →**

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- Presbyopia is the loss of ability to focus on near objects as a result of the natural aging process and affects more than 120 million people in the U.S.
- Phase 3 NEAR-1 and NEAR-2 clinical trials, involving over 600 patients, met primary and key secondary endpoints and serve as the basis for the submission

PONTE VEDRA, Fla., Jan. 3, 2023 /PRNewswire/ -- Orasis Pharmaceuticals, an emerging ophthalmic pharmaceutical company focused on developing a unique eye drop to improve near vision for people with presbyopia, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for investigational CSF-1 (low dose pilocarpine hydrochloride 0.4%).

"This NDA submission is a significant milestone for Orasis as we advance CSF-1 towards commercialization and achieving our goal of reshaping vision possibilities for patients," said Elad Kedar, Chief Executive Officer of Orasis Pharmaceuticals. "With more than 120 million people in the U.S. affected, we look forward to working with the FDA during its review process to ultimately provide an alternative treatment option for patients seeking flexibility in managing their presbyopia."

The NDA is based on data from the Phase 3 NEAR-1 and NEAR-2 clinical trials, involving more than 600 patients, which evaluated the efficacy and safety of CSF-1. Both trials met their primary and key secondary endpoints on Day 8, achieving statistically significant 3-line or more gain in distance-corrected near visual acuity (DCNVA), and no loss of 1-line or more in distance visual acuity. The most common treatment-related adverse events of headache and instillation site pain occurred in only 6.8% and 5.8% of participants, respectively. Of all CSF-1 participants, only 2.6% reported moderate treatment-related adverse events. All other adverse events were mild.



The Phase 3 NEAR-1 and NEAR-2 top-line results were previously announced earlier this year, and additional details of these studies will be presented at future medical meetings.

## **About CSF-1**

CSF-1 is a novel corrective eye drop candidate being investigated for the treatment of presbyopia. CSF-1 is a proprietary, preservative-free formulation of low-dose pilocarpine and multi-faceted vehicle designed to achieve an optimal balance between efficacy, safety and comfort. CSF-1 improves near visual acuity by pupil modulation, resulting in a "pinhole effect" and an increase in the depth of field, thus increasing the ability to focus on near objects.

## **About Presbyopia**

Presbyopia is the loss of ability to focus on near objects as a result of the natural aging process. It occurs mostly after the age of 40 when the crystalline lens of the eye gradually stiffens and loses flexibility. There are almost two billion people globally and more than 120 million people in the U.S. living with presbyopia. People with presbyopia experience blurred vision when performing daily tasks that require near visual acuity, such as reading a book, a restaurant menu, or messages on a smartphone. Presbyopia cannot be prevented or reversed, and it continues to progress gradually. Many existing treatment options can be either cumbersome or invasive, presenting a significant unmet need for quality-of-life improvement for people with presbyopia.

## **About Orasis Pharmaceuticals**

Orasis Pharmaceuticals is developing CSF-1, a corrective eye drop for the treatment of presbyopia. Orasis is led by a collaborative team of industry executives and eye care specialists with a broad range of experiences in research, development, and commercialization of pharmaceutical drugs, as well as finance and business development. Orasis is funded by a diverse group of sophisticated and experienced life science and healthcare investors including the ophthalmology focused venture capital fund Visionary Ventures, Sequoia Capital, SBI (Japan) Innovation Fund, Bluestem Capital, LifeSci Venture Partners, Maverick Ventures Israel, and other private investors. Orasis has offices in the U.S. and Israel. For more information, visit [www.orasis-pharma.com](http://www.orasis-pharma.com) and connect with us on LinkedIn.

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