aldeyra

TOP-LINE RESULTS

Phase 3 Dry Eye Disease Clinical Trial of Reproxalap

August 8, 2024

Nasdaq: ALDX

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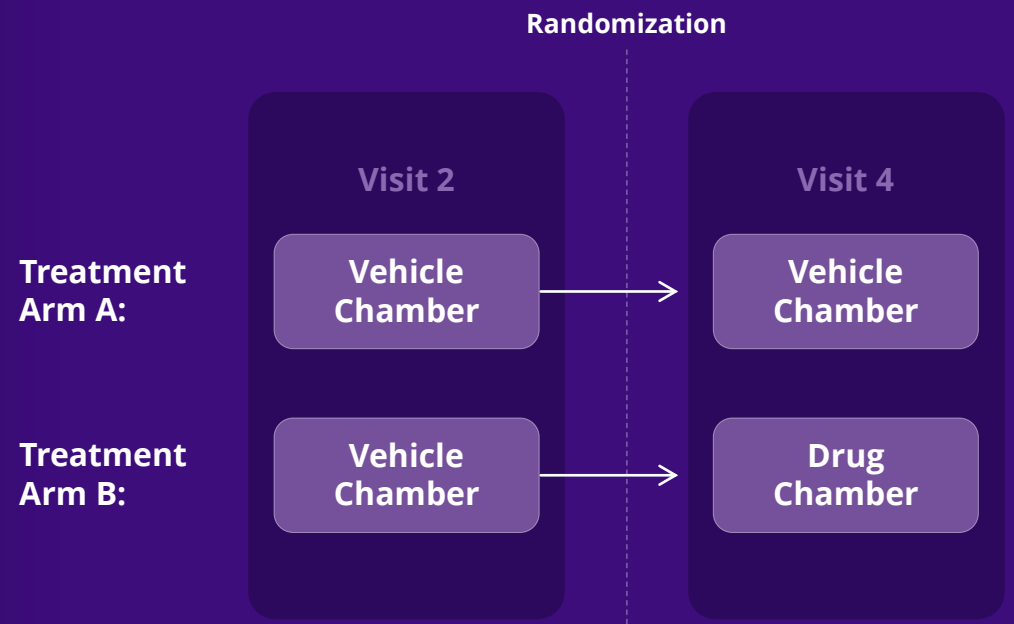
Reproxalap is an investigational new drug and is not available for commercial distribution.

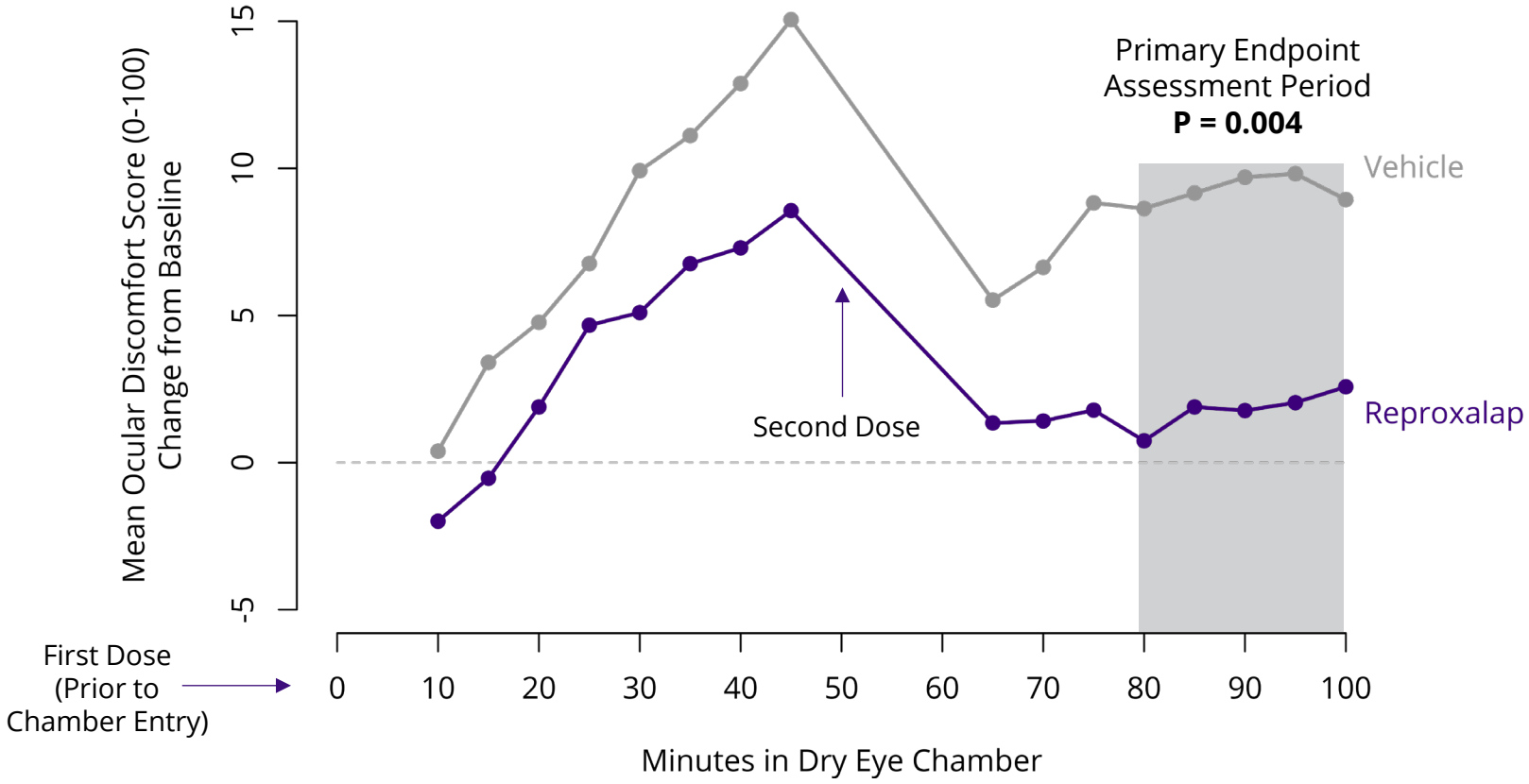
The Phase 3 Clinical Trial of Reproxalap in a Dry Eye Chamber was Designed to Satisfy the Requirements for NDA Resubmission†

Design	• Randomized, double-masked, vehicle-controlled dry eye chamber challenge
Dosing	• Visit 1: Medical screening • Visit 2: Vehicle dry eye chamber (dosing just before and 50 minutes after entry) • Visit 3: Four doses of randomized treatment (reproxalap or vehicle) • Visit 4: Randomized dry eye chamber (dosing just before and 50 minutes after entry)
Size	132 dry eye disease patients: 66 randomized to reproxalap, 66 randomized to vehicle
Primary Endpoint	Ocular discomfort score from 80 to 100 minutes
Other Endpoints	Safety



†NDA submission requirements depend, in part, on regulatory feedback. Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload and other potential review issues. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. NDA = New Drug Application.

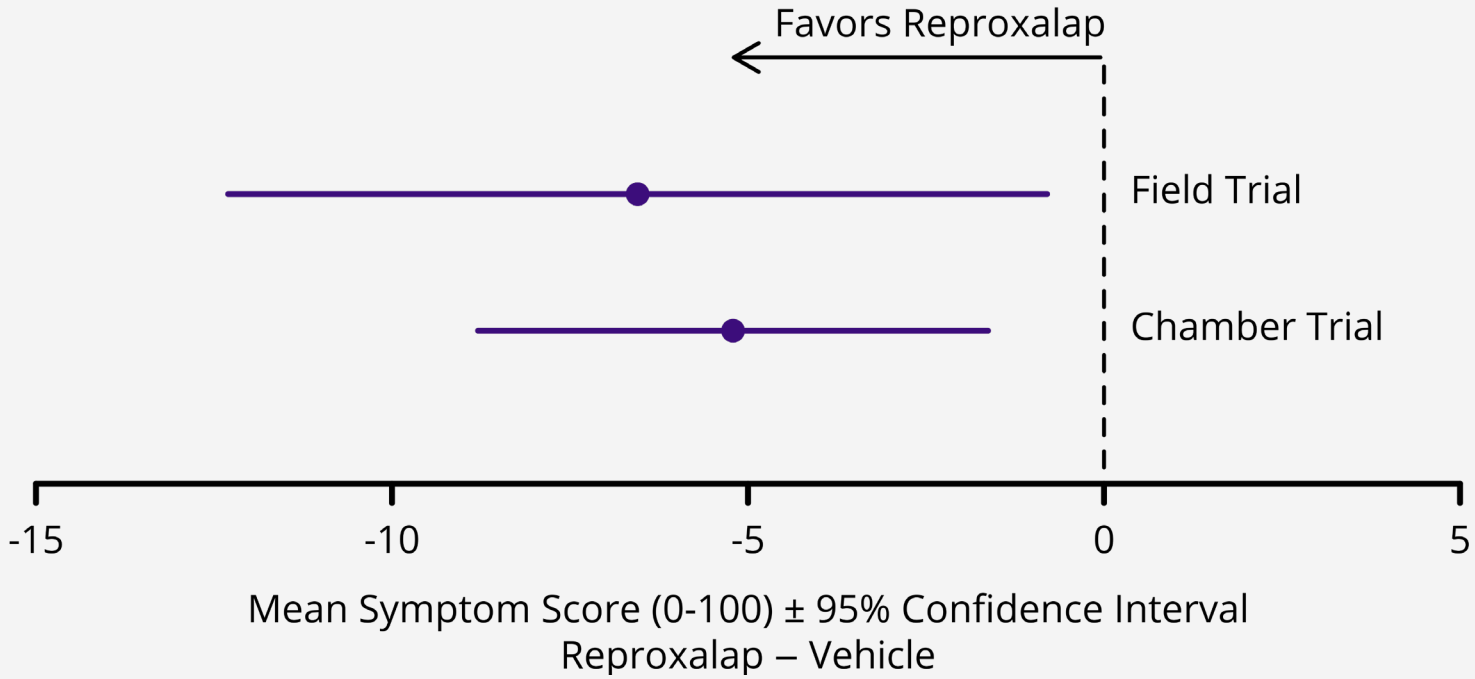
The Phase 3 Dry Eye Chamber Clinical Trial Achieved the Primary Endpoint of Ocular Discomfort



To our knowledge, the results represent the first positive Phase 3 clinical trial in a dry eye chamber with a symptom as a primary endpoint, and we believe that the results are supportive of the potential rapid clinical effect of reproxalap on reducing ocular discomfort.

P value derived from primary endpoint mixed model for repeated measures analysis. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Aldeyra Believes that Symptom Requirements for Dry Eye Disease NDA Resubmission Have Been Met



The Phase 3 dry eye chamber clinical trial symptom results are consistent with field trial symptom results previously reviewed by the FDA.

Estimates based on mixed model for repeated measures analysis adjusted for baseline and other factors specified in the Statistical Analysis Plans. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials. FDA = U.S. Food & Drug Administration.

Aldeyra Believes that Positive Results from the Phase 3 Clinical Trial Enable NDA Resubmission† of Reproxalap for Dry Eye Disease

- The dry eye chamber clinical trial was designed to satisfy the FDA's single resubmission requirement of "at least one additional adequate and well-controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye."
- Through the Special Protocol Assessment process and additional comments, the FDA provided feedback on the clinical trial protocol and statistical plan.
- Aldeyra believes the Phase 3 clinical trial satisfies the FDA's NDA resubmission requirement. NDA resubmission is anticipated in 2024. Based on FDA guidance, the anticipated review period for the potential NDA resubmission is expected to be six months.

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Aldeyra has Entered into an Exclusive Option Agreement with AbbVie Inc. for License to Develop and Commercialize Reproxalap

Key Terms of Reproxalap Option Agreement

Option for AbbVie to obtain:

- Co-exclusive license to develop, manufacture, and commercialize reproxalap in the U.S.
- Exclusive license to develop, manufacture, and commercialize outside the U.S.

Financial terms of license if option exercised:

- Upfront payment of $100 million less option fees
- $100 million milestone payment upon U.S. FDA approval in dry eye disease
- $200 million in additional regulatory and commercial milestones
- Profit and loss share (60% for AbbVie/40% for Aldeyra) from commercialization in U.S.
- Tiered royalties on net sales outside of U.S.

The option terminates on the earlier of (a) the 10th business day after the date on which Aldeyra received approval from the U.S. FDA of the NDA for reproxalap in dry eye disease and (b) the date that is 18 months after October 31, 2023. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Reproxalap Represents a Novel Potential Therapeutic Approach in Dry Eye Disease with Rapid Activity in Clinical Trials

Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.

Rapid and sustained symptom improvement

Broad symptomatic activity

Acute reduction of ocular redness

Dry Eye Disease Afflicts 39 Million or More Adults in the U.S.[†]

[†]Company estimates and Am J Ophthalmol. 2014;157(4):799-806. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,500 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.