



CLINICAL DEVELOPMENT PLAN UPDATE

Clinical Development Plan for
Resubmission of New Drug Application
for Reproxalap in Dry Eye Disease

March 28, 2024

Nasdaq: ALDX

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Clinical Development Plan for Resubmission of Reproxalap

New Drug Application for Dry Eye Disease

FDA Feedback

- The New Drug Application (NDA) Complete Response Letter received on November 27, 2023 stated that “at least one additional adequate and well-controlled study to demonstrate a positive effect on the treatment of ocular symptoms of dry eye” needed to be conducted; no other NDA deficiencies were identified by the U.S. Food and Drug Administration (FDA) in the Complete Response Letter.
- Feedback has been received from the FDA on a clinical trial protocol to assess symptoms in a dry eye chamber; Aldeyra believes that all substantive FDA comments on the protocol have been addressed.

Clinical Plan

- The dry eye chamber clinical trial, similar to the four previously completed dry eye chamber clinical trials with reproxalap, is expected to be initiated in the first half of 2024; results from the trial and, pending positive results, a potential NDA resubmission are expected in the second half of 2024.[†]
- An additional dry eye chamber clinical trial and a traditional six-week field clinical trial are expected to be conducted in parallel with the planned clinical trial as part of a contingency strategy designed to account for disease heterogeneity and potential differences across clinical sites and environment.[†]

[†]Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload and other potential review issues. The timing of clinical trials depends, in part, on the availability of clinical research facilities and staffing, the ability to recruit patients, and the number of patients in the trial. Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Phase 3 Clinical Trial of Reproxalap in a Dry Eye Chamber†

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

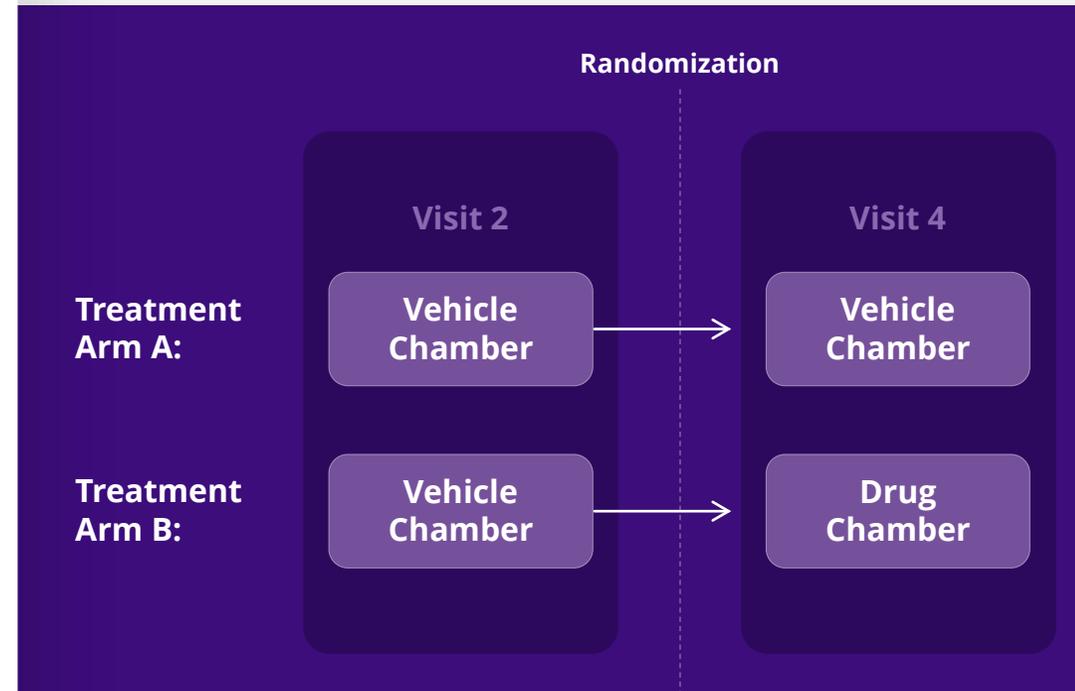
~100 dry eye disease patients

Primary Endpoint

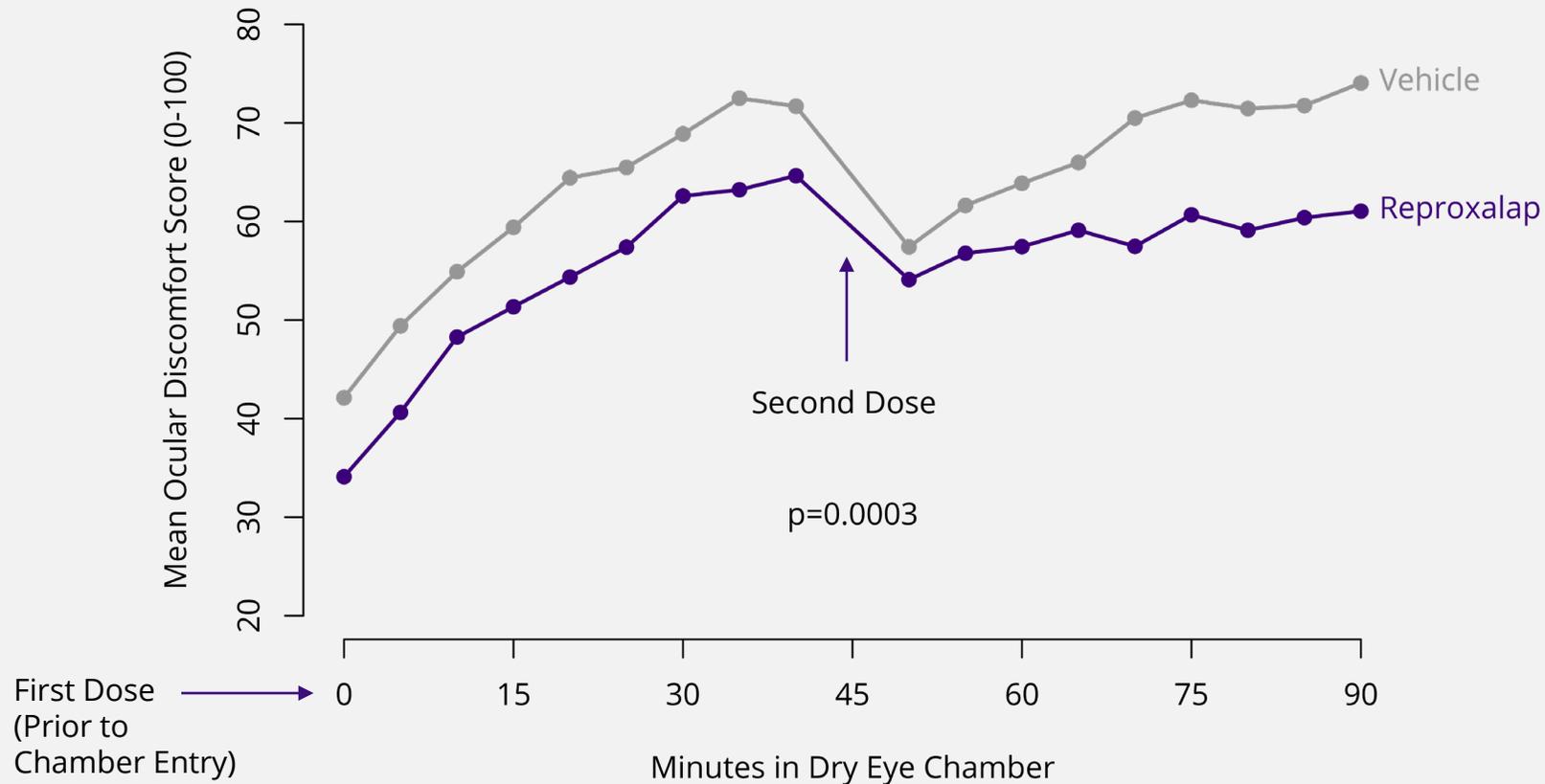
Ocular discomfort score

Other Endpoints

Safety



Based on Pooled Data from Four Dry Eye Chamber Trials, Ocular Discomfort Score was Lower with Reproxalap than with Vehicle



Ocular discomfort data are derived from four previously completed dry eye chamber clinical trials of reproxalap vs. vehicle, encompassing approximately 110 patients and incorporating trial conduct and statistical analysis amendments.



Topical ocular reproxalap is an investigational new drug candidate that has been studied in more than 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

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

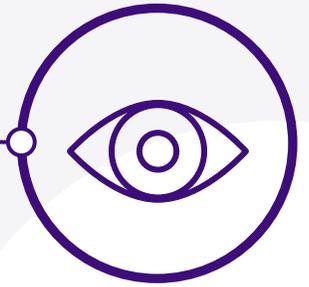
Potential advantages for patients and healthcare providers could effect a paradigm shift relative to standard of care.



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 2,400 patients with no observed safety concerns; mild and transient instillation site irritation is the most commonly reported adverse event in clinical trials.

Clinical and Regulatory Milestones



ReproXalap



Allergic Conjunctivitis

Positive Phase 3 INVIGORATE 2 trial top-line results announced



Dry Eye Disease

Proposed clinical trial top-line results and potential NDA resubmission expected in second half of 2024, pending clinical trial results, feedback from ongoing FDA discussions, and other factors^{† ‡}



ADX-629



Sjögren-Larsson Syndrome

Phase 2 clinical trial top-line results announced*



Moderate Alcohol-Associated Hepatitis

Open-label Phase 2 clinical trial results expected H2 2024[‡]



ADX-246



Atopic Dermatitis

Phase 1 clinical trial initiation expected in H1 2024[‡]



Metabolic Disease

Pre-clinical program initiated



ADX-248



Dry Age-Related Macular Degeneration/Geographic Atrophy

IND expected to be submitted in 2024



ADX-2191



Retinitis Pigmentosa

Type C Meeting with FDA expected in first quarter of 2024 to discuss pivotal clinical testing[†]

[†]Regulatory review and discussion timelines are flexible and subject to change based on the regulator's workload and other potential review issues. [‡]The timing of clinical trials depends, in part, on the availability of clinical research facilities and staffing, the ability to recruit patients, and the number of patients in the trial. *Investigator sponsored.