June 2019

Nasdaq: ALDX



# The SOLACE Trial in Noninfectious Anterior Uveitis

## Top-Line Results

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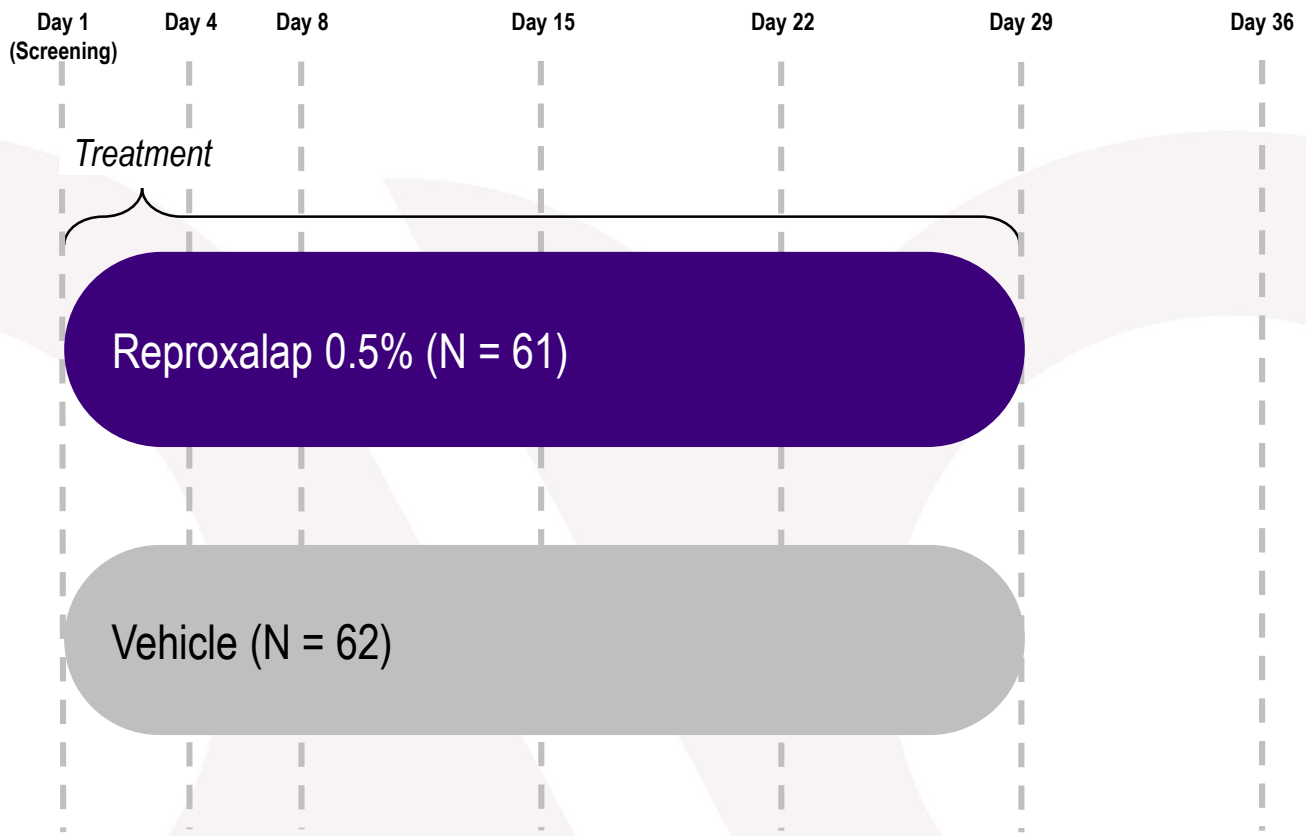
# Top-Line SOLACE Trial Results Summary

- No statistically significant difference was observed between the reproxalap group and the vehicle control group on the primary (time to cure) or secondary endpoints, due to high rates of disease resolution in vehicle-treated patients.
- For the primary and all time-to-event secondary endpoints, reproxalap was numerically favored over vehicle.
- The ocular inflammation improvement in the reproxalap group was consistent with Phase 2 trial results, which were statistically noninferior to corticosteroid therapy.
- Reproxalap activity in reducing ocular inflammation in patients with moderate disease, a pre-specified subgroup, was statistically superior to that of vehicle.
- Topical ocular reproxalap was observed to be safe and well tolerated, consistent with prior clinical trials.
- Aldeyra intends to discontinue the noninfectious anterior uveitis program in order to prioritize high-value Phase 3 ocular programs in dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy.

# The SOLACE Trial Design

- **Primary objective**
  - Evaluate efficacy of reproxalap ophthalmic solution (0.5%) on anterior chamber cell count (ACC) vs. vehicle
- **Inclusion highlights**
  - Acute endogenous noninfectious anterior uveitis with onset of symptoms within the previous 2 weeks
  - 6-50 ACC in the study eye
  - Intraocular pressure <21 mmHg
- **Dosing regimen**
  - Week 1 8x/day
  - Week 2 6x/day
  - Weeks 3-4 4x/day
  - Week 5 None
- **Endpoints**
  - Primary Endpoint: Time-to-cure (zero inflammatory cells in anterior chamber) without rescue
  - Secondary Time-to-Event Endpoints: one-point ACC grade reduction, flare cure, one-point flare grade reduction, requirement for rescue therapy




Further information can be found on www.clinicaltrials.gov: Trial #NCT03131154.

# Primary and Secondary Time to Event Endpoints – Overall Population

| Endpoint | Reproxalap | Vehicle | p value |
|---|---|---|---|
| Time to Cure (Anterior Cell Grade 0) | 15 days | 21 days | NS |
| Time to Anterior Cell Grade 1-Point Improvement | 7 days | 8 days | NS |
| Time to Flare Grade 0 | 8 days | 15 days | NS |
| Time to Flare Grade 1-Point Improvement | 5 days | 6 days | NS |
| Time to Rescue Therapy | 15 days | 12 days | NS |

Time to event represents 25$^{th}$ percentile Kaplan Meier estimates. Time to event p values represent log-rank tests. NS = Not Significant
Source: SOLACE noninfectious anterior uveitis clinical trial results

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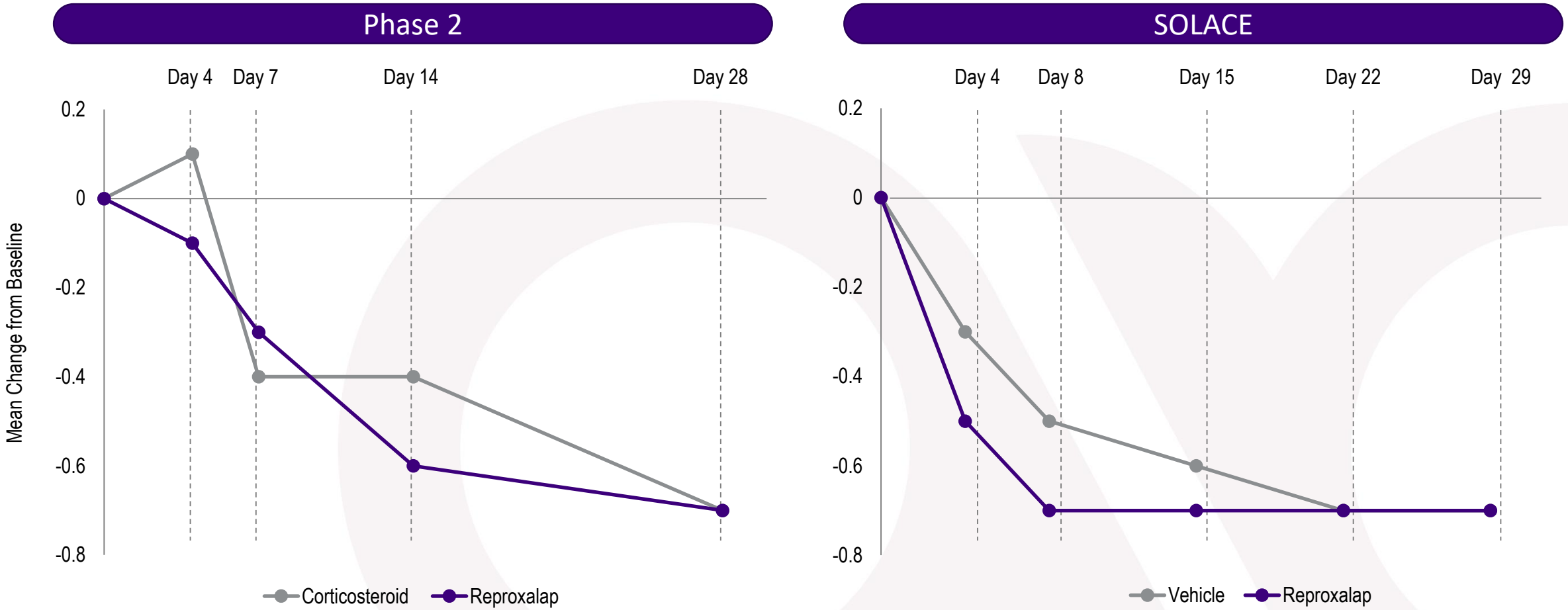
# Immune-Modulating Activity Observed in SOLACE Consistent with Phase 2 Trial Results, Which Were Statistically Noninferior to Corticosteroid

**Change from Baseline in Anterior Chamber Inflammatory Cell Grade**
ITT Population with Last Observation Carried Forward




ITT = Intention-To-Treat
Source: SOLACE noninfectious anterior uveitis clinical trial results and Phase 2 noninfectious anterior uveitis clinical trial results

# Primary and Secondary Time to Event Endpoints – Moderate Patients (a Pre-Specified Subgroup)

| Endpoint | Reproxalap | Vehicle | p value |
|---|---|---|---|
| Time to Cure (Anterior Cell Grade 0) | 15 days | 31 days | 0.08 |
| Time to Anterior Cell Grade 1-Point Improvement | 4 days | 6 days | 0.1 |
| Time to Flare Grade 0 | 5 days | > 32 days | 0.03 |
| Time to Flare Grade 1-Point Improvement | 5 days | 20 days | 0.1 |
| Time to Rescue Therapy | 15 days | 7 days | 0.06 |
| Combined | | | 0.0001 |

Moderate patients defined as patients with anterior chamber cell count grade of 2+.
Time to event represents 25$^{th}$ percentile Kaplan Meier estimates. Time to event p values represent log-rank tests. The combined p value is the fixed effect meta-analysis of log hazard ratios.
Source: SOLACE noninfectious anterior uveitis clinical trial results

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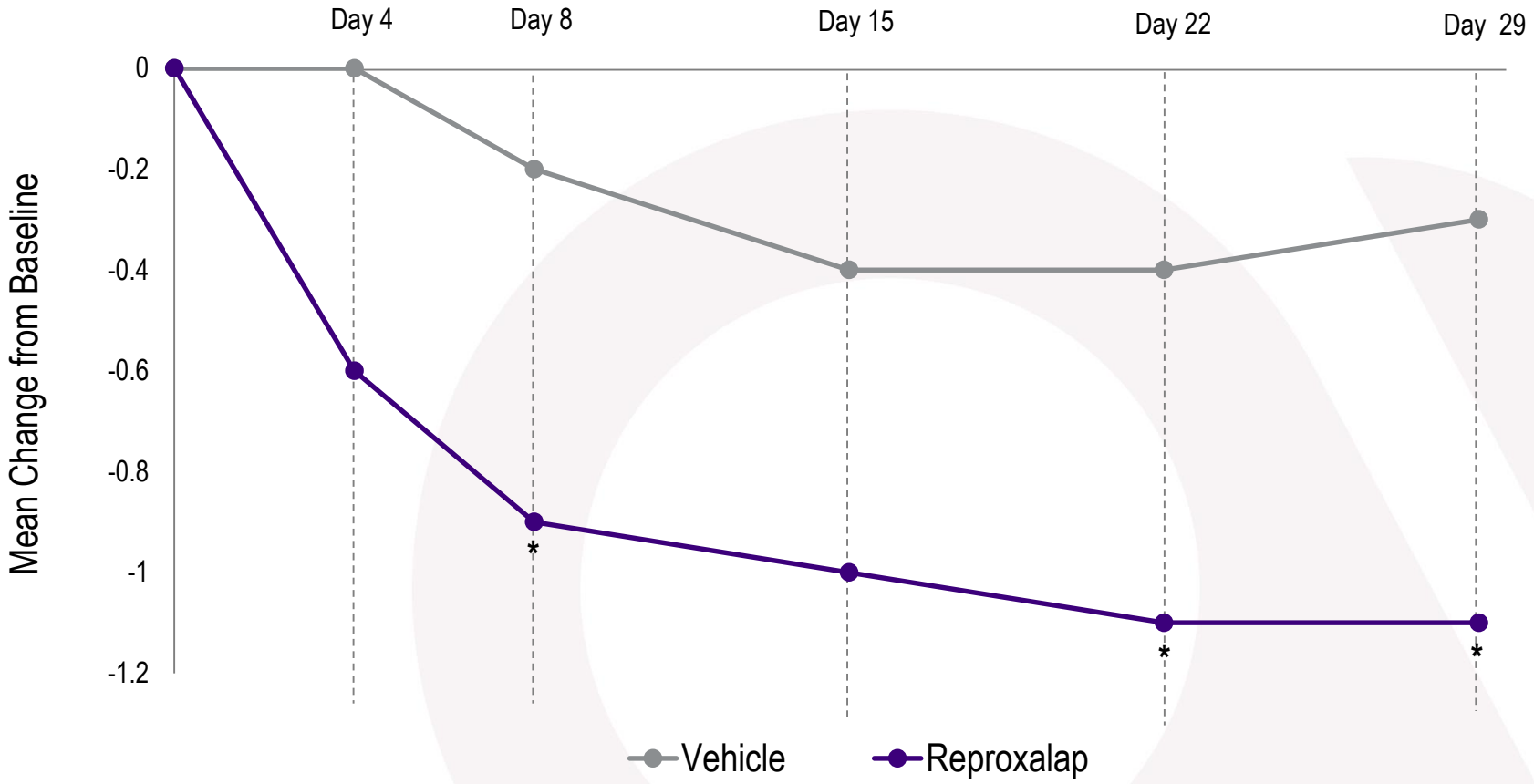
# Immune-Modulating Activity of Reproxalap was Statistically Superior to that of Vehicle in Patients with Moderate Severity (a Pre-Specified Subgroup)

**Change from Baseline in Anterior Chamber Inflammatory Cell Grade**

Moderate Severity ITT Population with Last Observation Carried Forward




| Proportion Cured (Grade 0 = no inflammatory cells observed) | |
|---|---|
| Week 4 Grade 0 | Percent of Subjects |
| Reproxalap | 53% |
| Vehicle | 25% |

**MMRM p = 0.0489**

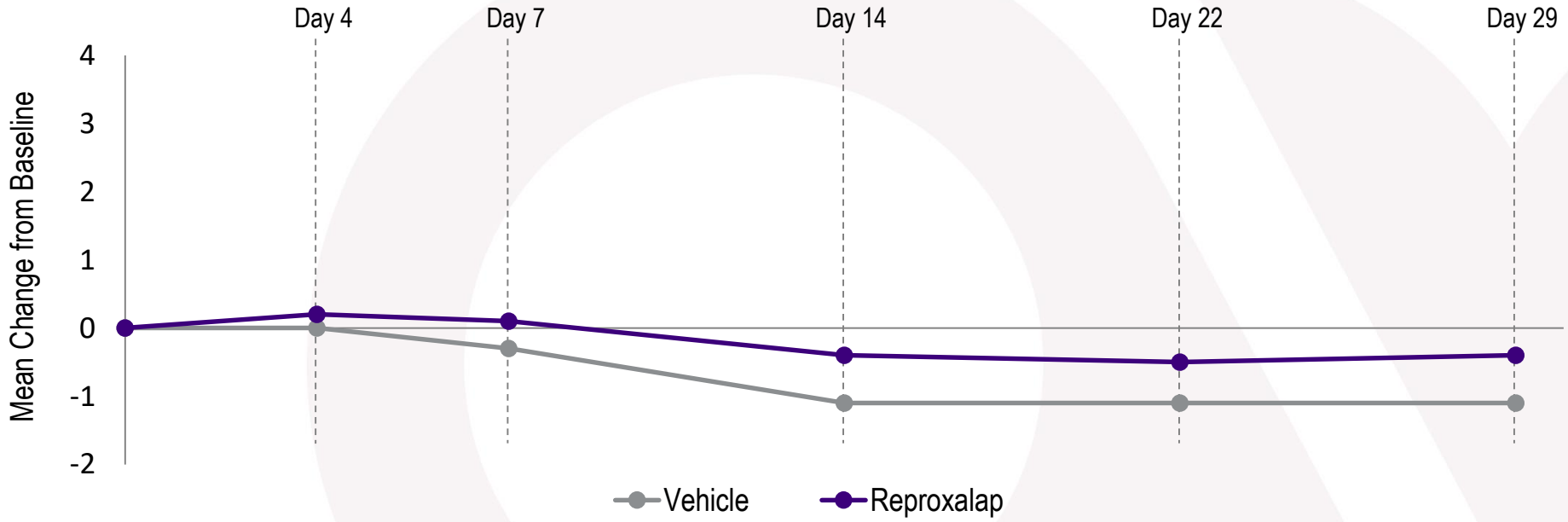
Moderate severity defined as patients with anterior chamber cell count grade of 2+.
Source: SOLACE noninfectious anterior uveitis clinical trial results

*p<0.05
MMRM = Mixed Effect Model Repeated Measures

# Topical Ocular Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in SOLACE

- Now administered to over 800 patients across nine completed clinical trials
- No observed safety or tolerability concerns, consistent with previous clinical trials

**Change from Baseline in Intraocular Pressure (mmHg)**
Safety Population




Source: SOLACE noninfectious anterior uveitis clinical trial results

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# Ocular Program Status

Aldeyra intends to prioritize high-value Phase 3 ocular programs

## Dry Eye Disease

- **Positive Phase 2b** clinical trial results, announced September 2018
- **RENEW Phase 3 clinical trial program ongoing**

## Allergic Conjunctivitis

- **Positive ALLEVIATE Phase 3** clinical trial results, announced March 2019
- **Positive allergen chamber** clinical trial results, announced June 2019
- **Subsequent Phase 3 trial expected to be confirmed H2 2019**

## Proliferative Vitreoretinopathy

- **Phase 3 clinical program initiation expected H2 2019**