# SOL-1 & SOL-R Pivotal Phase 3 Trials Evaluating OTX-TKI for wAMD

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**This presentation discusses investigational product candidates in development. Their efficacy and safety profiles have not been established, and they have not been approved for marketing by the FDA or any other Health Authority.**

# SOL-1 Design: OTX-TKI First Registration Study in Wet AMD

***Superiority Study*** *Comparing a Single OTX-TKI Dose to a Single Aflibercept (2 mg) Dose*

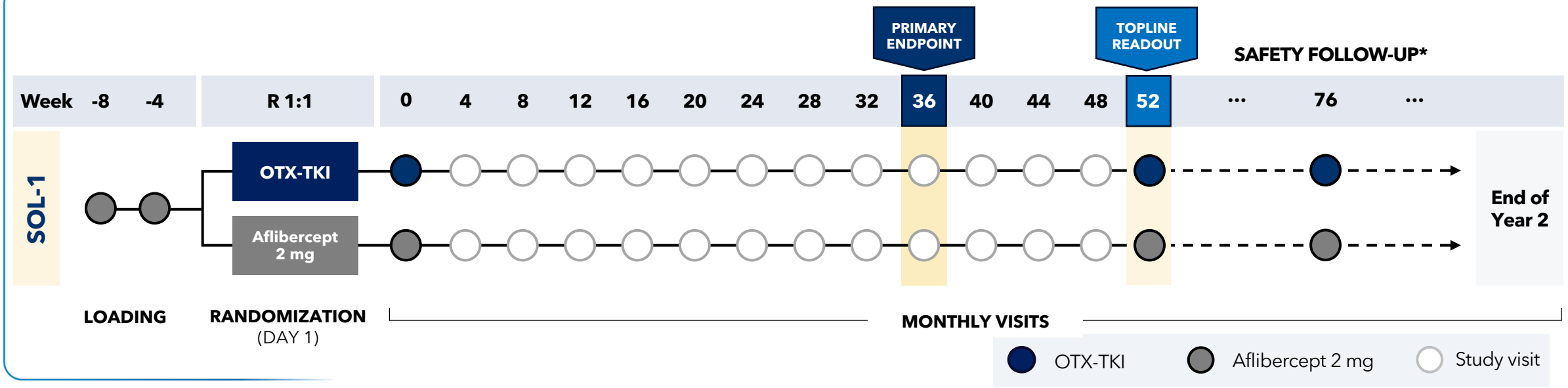
## DESIGN

Two-arm trial with ~300 total subjects randomized 1:1

## PRIMARY ENDPOINT (WEEK 36)

Demonstrate that a single OTX-TKI dose is superior to a single aflibercept 2 mg dose based on proportion of subjects who maintained visual acuity, defined as <15 ETDRS letters of BCVA loss from baseline at Week 36

## TRIAL SCHEMATIC




*Trial subjects and designated personnel will remain masked through end of year 2.
AMD (age-related macular degeneration); BCVA (best-corrected visual acuity); ETDRS (Early Treatment Diabetic Retinopathy Study).

# SOL-1 Design: OTX-TKI First Registration Study in Wet AMD

***Superiority Study*** *Comparing a Single OTX-TKI Dose to a Single Aflibercept (2 mg) Dose*

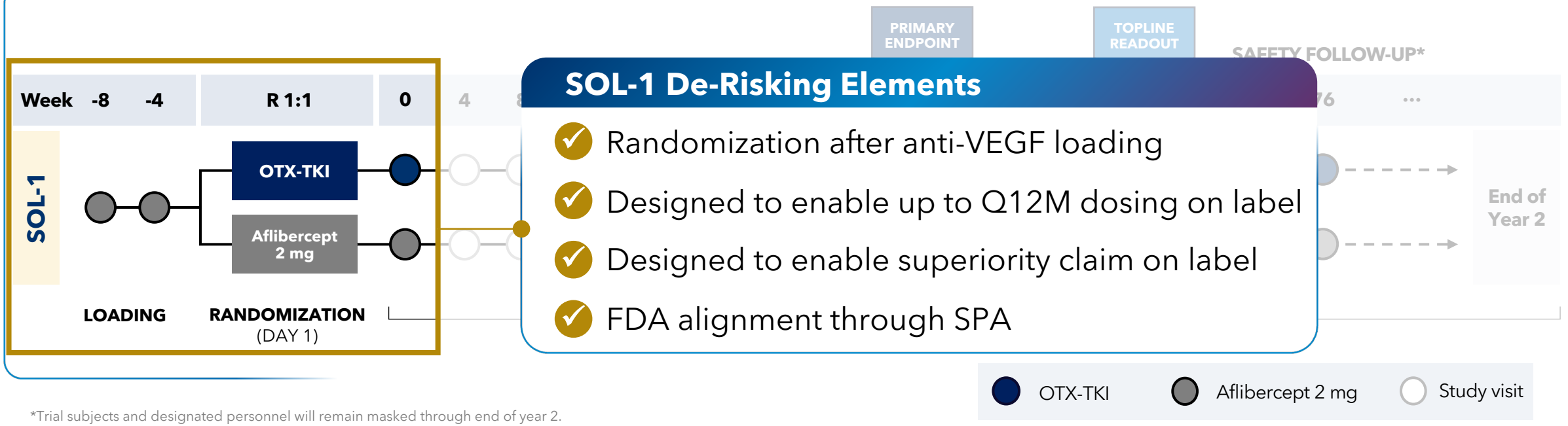
## SOL-1 STATUS

**Fully randomized**
as of Dec 2024

**344 subjects** randomized across
**>100 sites** in U.S. and Argentina

**Topline data**
expected **1Q 2026**

## TRIAL SCHEMATIC




### SOL-1 De-Risking Elements

- ✓ Randomization after anti-VEGF loading
- ✓ Designed to enable up to Q12M dosing on label
- ✓ Designed to enable superiority claim on label
- ✓ FDA alignment through SPA

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AMD (age-related macular degeneration); BCVA (best-corrected visual acuity); ETDRS (Early Treatment Diabetic Retinopathy Study).

# SOL-R Design: OTX-TKI Second Registration Study in Wet AMD

***Non-Inferiority Study*** *Comparing OTX-TKI Q24W to Aflibercept (2mg) Q8W at W56*

## DESIGN

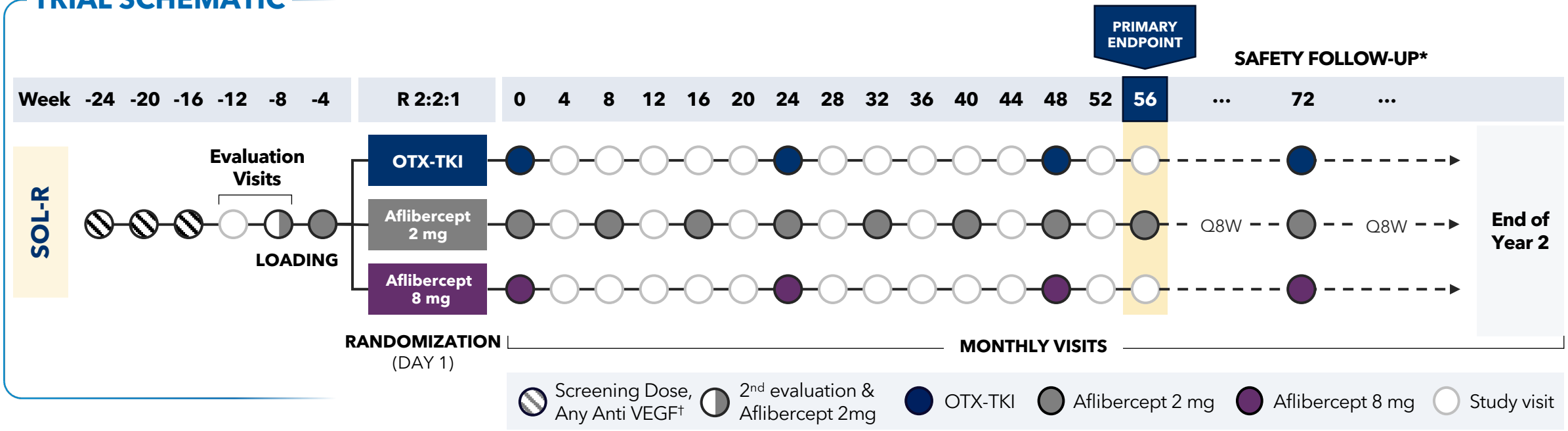
Three-arm trial with 555 total subjects randomized 2:2:1

## PRIMARY ENDPOINT (WEEK 56)

Demonstrate that OTX-TKI is non-inferior to fixed-dose aflibercept 2mg Q8W with respect to mean change in BCVA at Week 56 from baseline in wet AMD patients

Non-inferiority margin for the lower bound is -4.5 letters in BCVA at Week 56

## TRIAL SCHEMATIC

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AMD (age-related macular degeneration); BCVA (best-corrected visual acuity); ETDRS (Early Treatment Diabetic Retinopathy Study).

# SOL-R Design: OTX-TKI Second Registration Study in Wet AMD

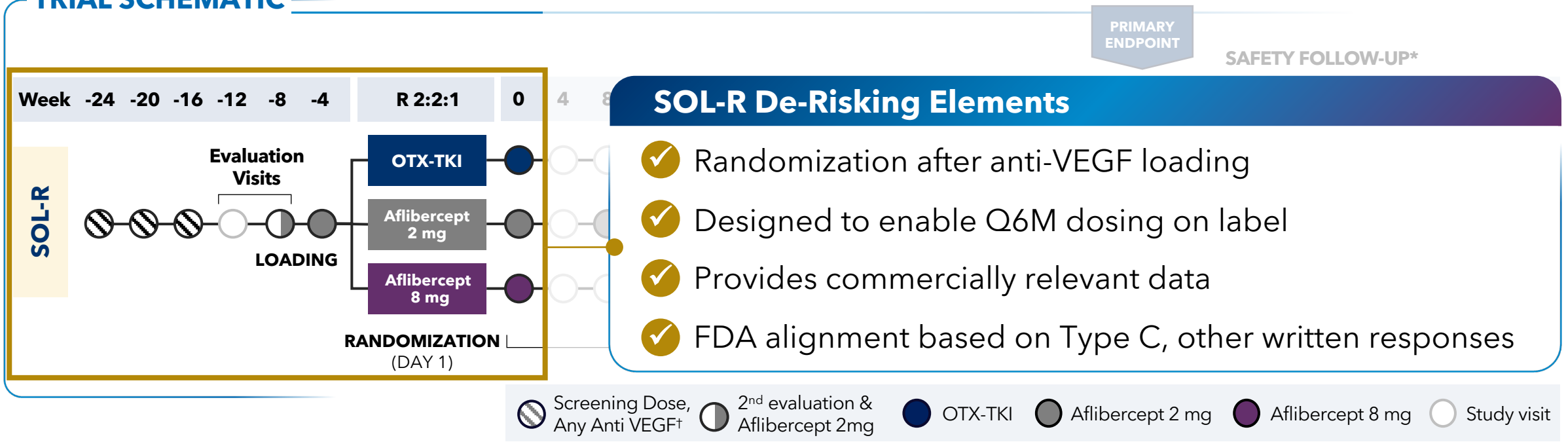
***Non-Inferiority Study*** *Comparing OTX-TKI Q24W to Aflibercept (2mg) Q8W at W56*

## SOL-R STATUS

Initially enrolled SOL-1 randomization failures
**Opened direct enrollment in Nov 2024**

**Closed enrollment** end of May 2025 with loading and randomization ongoing

## TRIAL SCHEMATIC

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# SOL Clinical Program

## *De-risking Registrational Program*

SOL

*Complementary trials with measures taken to de-risk outcomes*

### SOL-1 + SOL-R

- Compelling Phase 1 data
- De-risking Phase 3 designs
- De-risking regulatory path

**Taken together, DIFFERING yet COMPLEMENTARY study designs contribute to a more comprehensive characterization of OTX-TKI across patient populations**

# THANK YOU!