



CLEARSIDE  
BIOMEDICAL

**Clearside Biomedical**

**Update on CLS-AX for wAMD**



# Key Takeaways for CLS-AX Program for Wet AMD

Suprachoroidal delivery of **axitinib** injectable suspension



Suprachoroidal injections deliver therapy to the **back of the eye** without any implants or devices in the vitreous

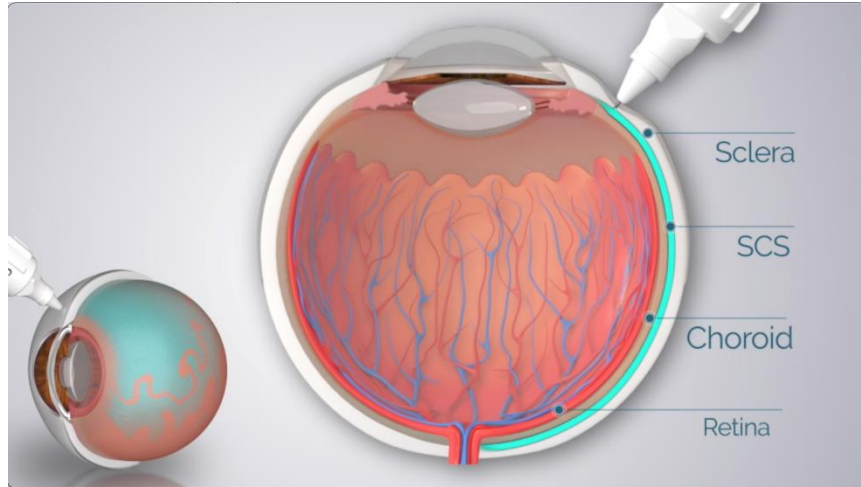
ODYSSEY<sup>1</sup> will evaluate patients for 36 weeks, in line with the guidance from the FDA

ODYSSEY trial design includes retreatment with CLS-AX rather than rescue only

Top line data from ODYSSEY expected **Q3 2024**

Patients recruited with an emphasis on **active disease** to target **clinically-relevant** patient population with **need for treatment**

# SCS Microinjector®: Drug/Device Combination with Proven Versatility



## SUPRACHOROIAL SPACE INJECTION

Novel SCS Microinjector® shows a demonstrated ability for precise delivery into the suprachoroidal space (SCS)

- ✓ **6 ongoing clinical trials with 4 potential therapies in 5 indications:**  
Wet AMD, UME, DME, DR, Choroidal Melanoma
- ✓ **Safety profile of SCS Microinjector comparable to intravitreal injections<sup>1</sup>**
- ✓ **Well-accepted by retinal physicians with thousands of injections performed to date**
- ✓ **30-gauge needle equivalent to most commonly used intravitreal injections**  
Smaller than TKI competitors in development

# Benefits for Patients and Physicians Using SCS Microinjector<sup>®</sup> Delivery



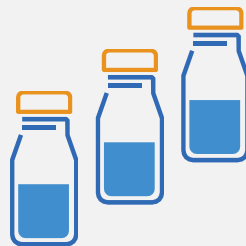
## Enhanced Safety

Much lower risk of endophthalmitis as direct contact to immune system vs intravitreal injection



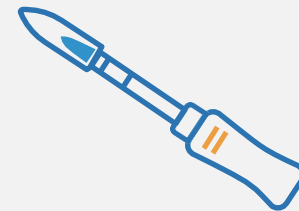
## Injectate Flows to Back of the Eye

Reduced risk of floaters, snow globe effect, or other visual disturbances



## No Implants or Devices in the Vitreous

Can be easily re-dosed for potentially longer durability



## Injection Similar to Intravitreal

Advanced technology requires only a few seconds longer for each injection

# CLS-AX OASIS + Extension Trial: Demonstrated Excellent Safety Profile and Promising Durability and Biologic Effect

## SAFETY DATA

- Excellent safety profile at all doses and timepoints
- No Serious Adverse Events
- No dose limiting toxicities
- No Adverse Events (AEs) from inflammation
- No AEs related to intraocular pressure

## DURABILITY

- Patients not requiring additional therapy:
  - $\geq 3$  Months: 11/12 (92%)
  - $\geq 4$  Months: 10/12 (83%)
  - $\geq 6$  Months: 8/12 (67%)



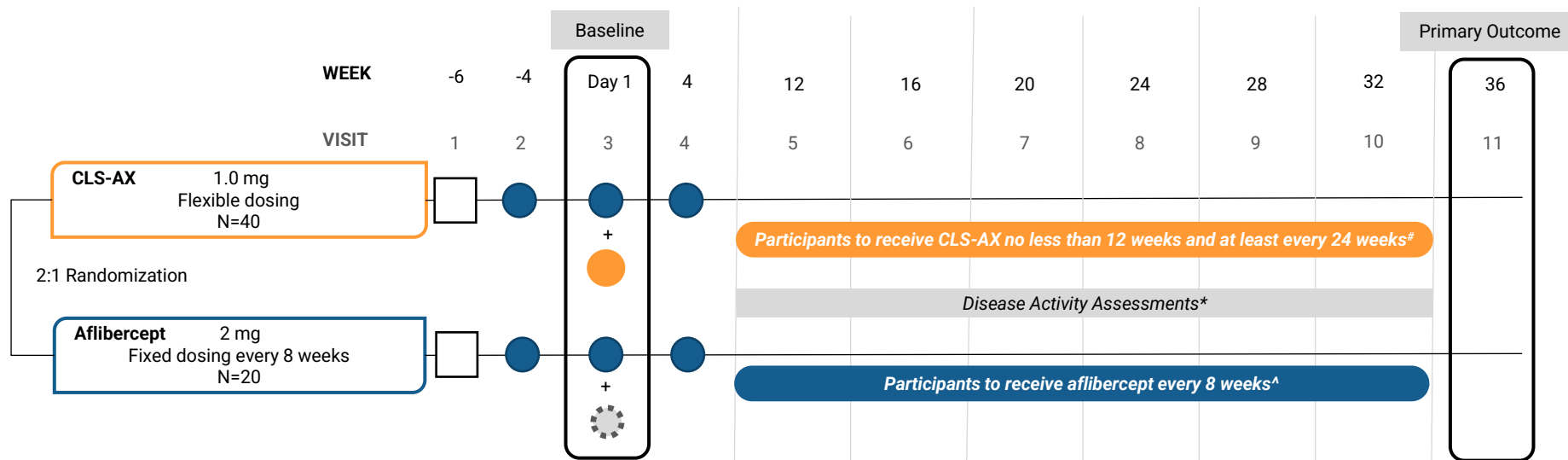
## BIOLOGIC EFFECT

- Stable mean Best Corrected Visual Acuity (BCVA)
- Stable mean Central Subfield Thickness (CST)
- On OCT, anatomical signs of TKI biologic effect observed in anti-VEGF treatment-experienced sub-responders

## REDUCED TREATMENT BURDEN

- $\geq 72\%$  reduction in treatment burden In OASIS, to 3 months:
- **77% to 85% reduction in treatment burden in Extension Study, to 6 months**

# ODYSSEY Trial Designed to Provide Data for Phase 3



□ Screening visit

● CLS-AX 1.0 mg Suprachoroidal Injection (SCS)

● Aflibercept 2 mg Intravitreal Injection (IVT)

⊗ Sham Procedure

\* Disease Activity Assessments (DAA): Conducted at Week 12 through 32 to determine need for supplemental treatment.

# In CLS-AX arm, following 3 loading doses of aflibercept and initial dose of CLS-AX at Baseline, participants will receive CLS-AX at least every 24 weeks unless more frequently required based on DAA; if disease is active and participant is <12 weeks since last CLS-AX injection, participant receives dose of aflibercept; if disease is active and participant is >12 weeks since last CLS-AX injection, participant receives dose of CLS-AX.

^ In aflibercept arm, following 3 loading doses of aflibercept, participants will receive aflibercept on fixed dosing regimen every 8 weeks unless more frequently required based on DAA; if disease is active, participant receives dose of aflibercept.

# Multiple Dosing Requirement Helps Inform Phase 3 Development Program

Disease Activity Assessments (DAA) conducted every 4 Weeks starting at Week 12 to determine need for supplemental treatment.

## CLS-AX Arm

- Ability to re-treat with CLS-AX if needed based on DAA
  - Weeks 4-12: Re-treat with aflibercept
  - Weeks 12-24: Re-treat with CLS-AX
- Protocol mandates re-dosing
  - Week 24: Re-dose with CLS-AX if not previously re-treated

## Aflibercept Control Arm

- Protocol mandates on-label dosing with aflibercept every 8 weeks unless re-treatment required based on DAA

# Key Takeaways for CLS-AX Program for Wet AMD

Suprachoroidal delivery of **axitinib** injectable suspension



- **Suprachoroidal injections deliver therapy to the back of the eye without any implants or devices in the vitreous**
- **ODYSSEY<sup>1</sup> will evaluate patients for 36 weeks, in line with the guidance from the FDA**
- **ODYSSEY trial design includes retreatment with CLS-AX rather than rescue only**
- **Top line data from ODYSSEY expected Q3 2024**
- **Patients recruited with an emphasis on active disease to target clinically-relevant patient population with need for treatment**