



CLEARSIDE BIOMEDICAL

OASIS

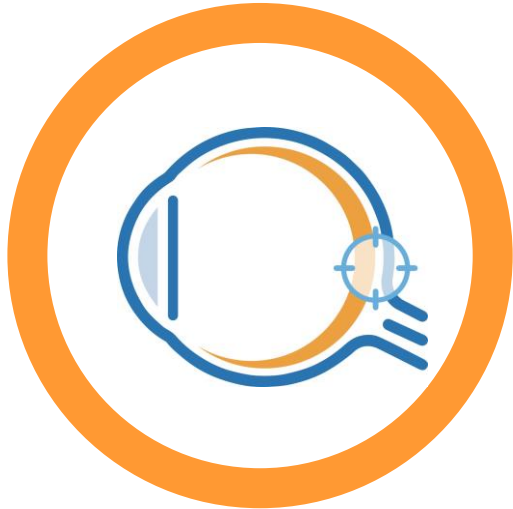
**OASIS Phase 1/2a Clinical Trial
6-Month Extension Study Results
February 2, 2023**



Forward-Looking Statements

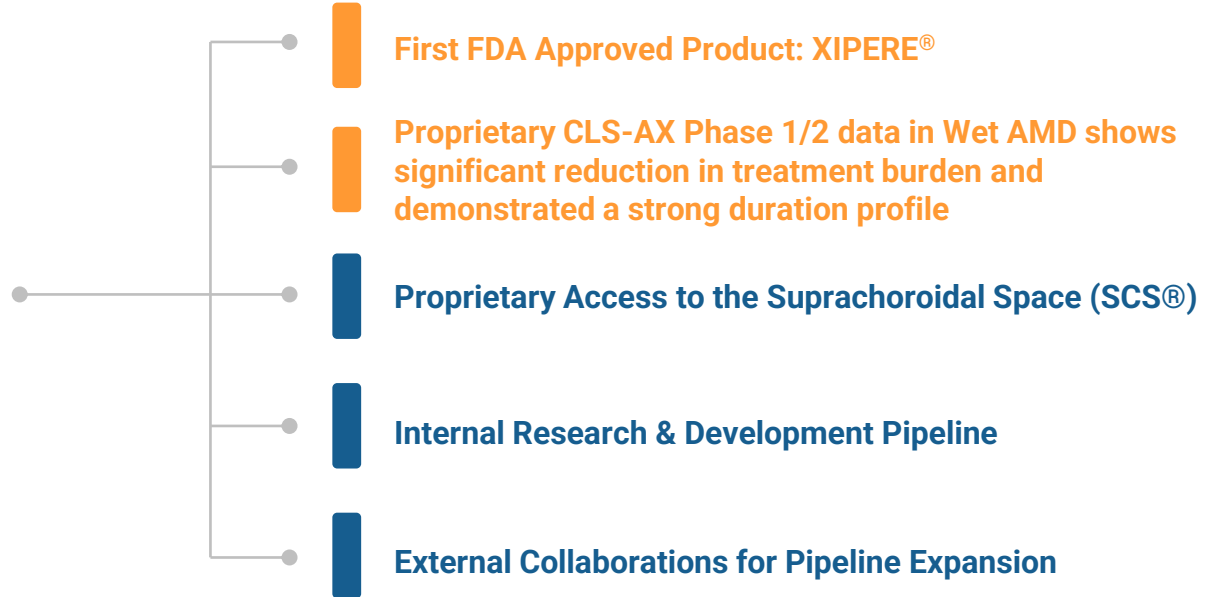
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Developing and Delivering Treatments that Restore and Preserve Vision for Serious Back of the Eye Diseases



Versatile Therapeutic Platform

SCS Microinjector[®] with proprietary drug formulations target the suprachoroidal space



OASIS (3 Month) and Extension Study (6 Month) Cohorts 3 and 4: Promising CLS-AX Safety Data, 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

- In OASIS, to 3 months:
 - $\geq 72\%$ reduction in treatment burden
- In Extension Study, to 6 months:
 - $\geq 77\%$ reduction in treatment burden
 - Patients not requiring additional therapy:
 - ≥ 3 Months: 11/12 (92%)
 - ≥ 4 Months: 10/12 (83%)
 - ≥ 6 Months: 8/12 (67%)
 - > 6 Months: 6/12 (50%)



BIOLOGIC EFFECT

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

NEXT STEPS

- Expect to initiate Phase 2b clinical trial in Q1 2023 with primary endpoint readout anticipated in mid-2024

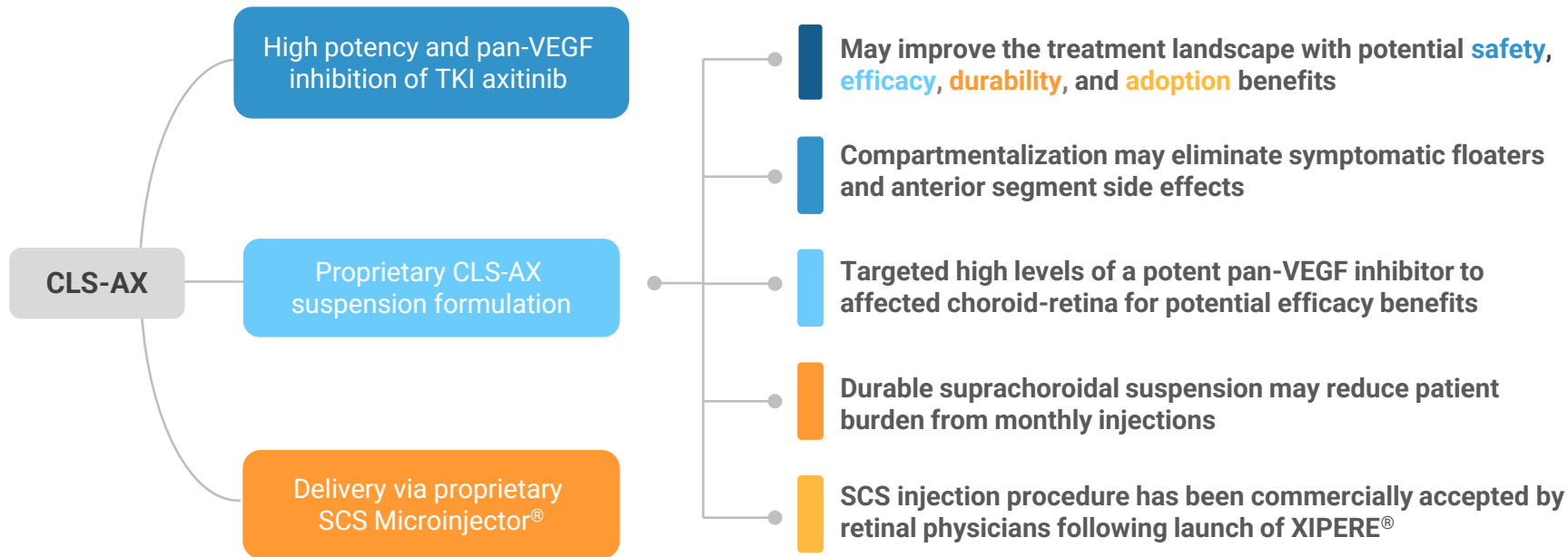
CLS-AX

(axitinib injectable suspension)
for Suprachoroidal Injection

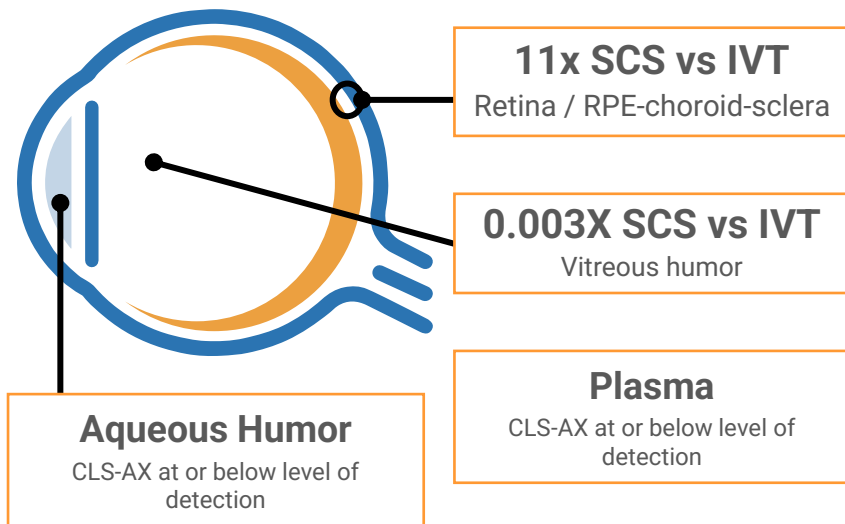


CLS-AX (axitinib injectable suspension) for Suprachoroidal Use

Leveraging a Highly Potent Pan-VEGF Inhibitor with Suprachoroidal Delivery



CLS-AX Injected Suprachoroidally Provides Targeted Delivery Relative to Intravitreal Injection at Same Dose

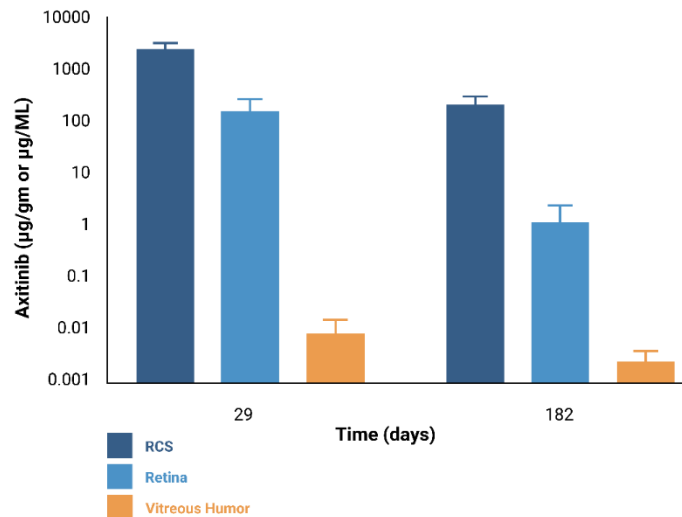


Rabbit Model Values: area under the curve ratios, SCS / IVT

SCS : 1 mg/eye, 100 μ L. | IVT: 1 mg/eye, 25 μ L
 Single bilateral injection, 1-wk rabbit PK studies

CLS-AX has Potential for Meaningful Durability CLS-AX Levels to 6 Months

High Retina Levels: Sufficient to block VEGF pathway
 Low Plasma Levels: <1 ng/mL



Rabbit toxicology study with single bilateral suprachoroidal injection of axitinib, 1.05 mg/eye (n=4 eyes/ timepoint)

OASIS and Extension Study: CLS-AX Phase 1/2a Clinical Trial in Treatment-Experienced Wet AMD Patients with Active Disease at Screening

TRIAL DESIGN AND OBJECTIVES

- **Open-label study** with a primary endpoint to evaluate safety and tolerability of escalating single doses of CLS-AX administered through suprachoroidal injection following IVT aflibercept
- Wet AMD patients with ≥ 2 anti-VEGF treatments in the prior 4 months, reading center confirmation of persistent active disease
- Dose-escalation of CLS-AX (in mg): Cohort 1 at 0.03; Cohort 2 at 0.1; Cohort 3 at 0.5; Cohort 4 at 1.0
- Secondary endpoints: visual function, ocular anatomy, and need for additional treatment
- Monthly assessment for additional treatment with aflibercept: loss from best measurement of ≥ 10 letters in BCVA with exudation; increase in CST >75 microns; a vision-threatening hemorrhage
- **Extension study:** A total of 6 months' follow-up for patients in Cohorts 2, 3, & 4 who chose to continue for an additional 3 months



OASIS Enrolled Heavily anti-VEGF Treatment-Experienced Wet AMD Patients

Patients were sub-responders with active disease at screening confirmed by reading center

Why target this patient population instead of treatment naïve or patients with controlled disease?

- Patients have a high need for effective therapy with lower treatment burden
- Minimizes the risk of false signals of biologic effect
- Facilitates assessment for biological effect in a difficult-to-treat nAMD patient population
- Facilitates assessment of an appropriate dose, based on safety and biologic effect
- Represents a significant number of patients in clinical practice, with >30% sub-responders
- Supports future clinical trials

Desired outcomes in this heavily treated patient population:

- Demonstrate safety and tolerability of CLS-AX
- Maintain stability of visual acuity and central subfield thickness with lower treatment burden

Enrolling difficult to treat anti-VEGF sub-responders allowed observation of possible signs of biologic effect while minimizing false signals

Enrolled Patients All with Active Disease at Screening and Confirmed by Independent Reading Center

Demographics and Wet AMD History

Wet AMD Disease Characteristics	COHORT 1: 0.03 mg	COHORT 2: 0.1 mg	COHORT 3: 0.5 mg	COHORT 4: 1.0 mg
No. of participants	6	5	8	8
Mean age (range), years	81.8 (66-93)	78.2 (65-90)	86.3 (75-97)	76.5 (66-83)
Mean baseline best corrected visual acuity (range), letters	59.0 (29-74)	65.6 (52-75)	58.5 (37-74)	65.8 (50-74)
Mean baseline central subfield retinal thickness (range), μm	231.2 (208-294)	209.4 (184-227)	202.0 (175-238)	218.8 (152-295)
Mean duration of wAMD diagnosis (range), months	50.13 (12.4-110.3)	49.78 (24.7-81.3)	66.64 (6.8-102.1)	48.21 (4.5-132.8)
Number of anti-VEGF injections reported prior to CLS-AX administration on Day 1, mean (range)	26.8 (7-41)	24.2 (12-39)	37.0 (6-90)	28.8 (5-89)
Annualized number of anti-VEGF injections prior to CLS-AX administration on Day 1, mean (range)	9.36 (6.3-12.7)	9.54 (5.4-12.2)	8.47 (4.9-11.8)	11.96 (8.9-13.6)

Extension Study: Demographics and Wet AMD History

Wet AMD Disease Characteristics	COHORT 2: 0.1 mg	COHORT 3: 0.5 mg	COHORT 4: 1.0 mg	Total
No. of participants	2	7	5	14
Mean age (range), years	74.0 (70-78)	87.9 (81-97)	79.6 (74-83)	82.9 (70-97)
Mean baseline best corrected visual acuity (range), letters	60.0 (52-68)	59.0 (37-74)	71.2 (69-74)	63.5 (37-74)
Mean baseline central subfield retinal thickness (range), μm	213.5 (200-227)	201.9 (175-238)	214.8 (197-234)	208.1 (175-238)
Mean duration of wAMD diagnosis (range), months	44.30 (33.9-54.7)	67.29 (6.8-102.1)	36.42 (6.1-103.4)	52.98 (6.1-103.4)
Number of anti-VEGF injections reported prior to CLS-AX administration on Day 1, mean (range)	23.0 (12-34)	38.9 (6-90)	33.2 (6-89)	34.6 (6-90)
Annualized number of anti-VEGF injections prior to Enrollment, mean (range)	8.81 (5.4-12.2)	8.84 (4.9-11.9)	12.01 (10.5-13.1)	9.97 (4.9-13.1)

OASIS Results: Safety, Durability, & Treatment Burden Reduction



CLS-AX Demonstrated a Positive Safety Profile in All Four Cohorts

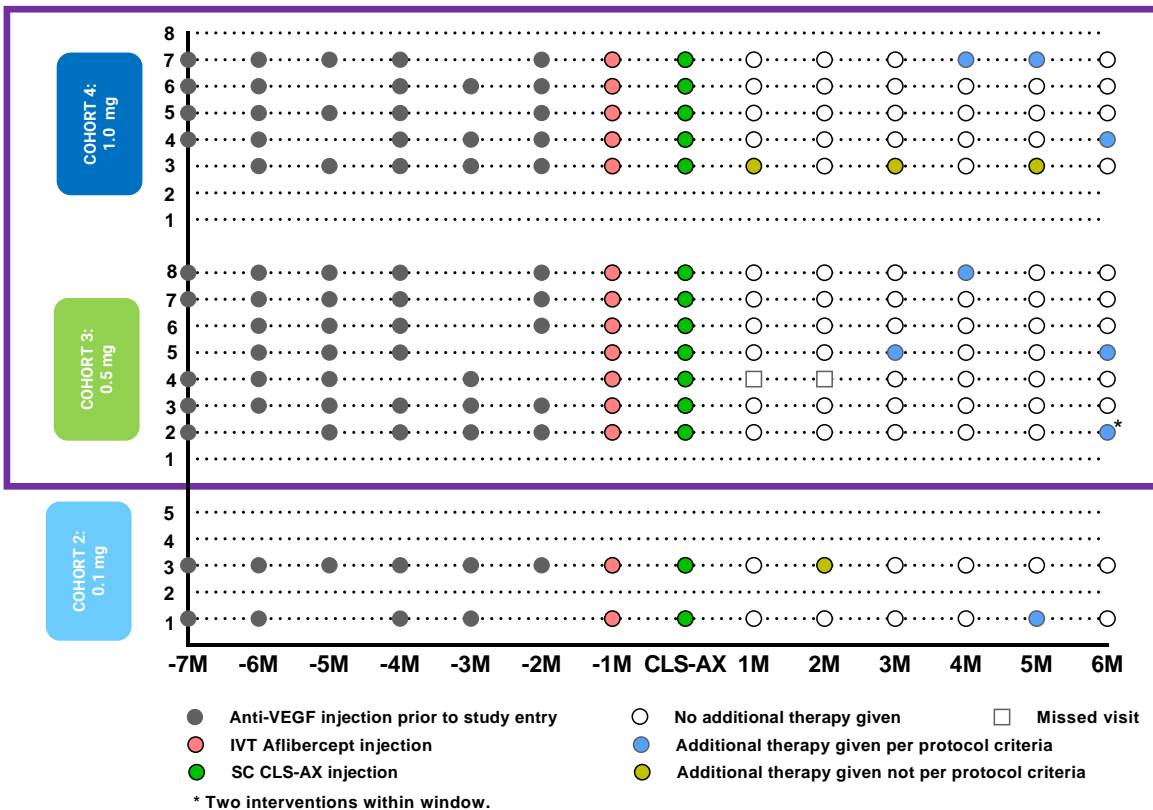
3-Month & 6-Month Extension Study Data

SAFETY DATA

Excellent Safety Profile at all doses and timepoints

- No serious adverse events (SAEs)
- No treatment emergent adverse events (TEAEs) related to study treatment
- No dose limiting toxicities
- No adverse events related to inflammation, vasculitis or vascular occlusion
- No vitreous “floaters” or dispersion of CLS-AX into the vitreous
- No retinal detachment
- No endophthalmitis
- No adverse events related to intraocular pressure

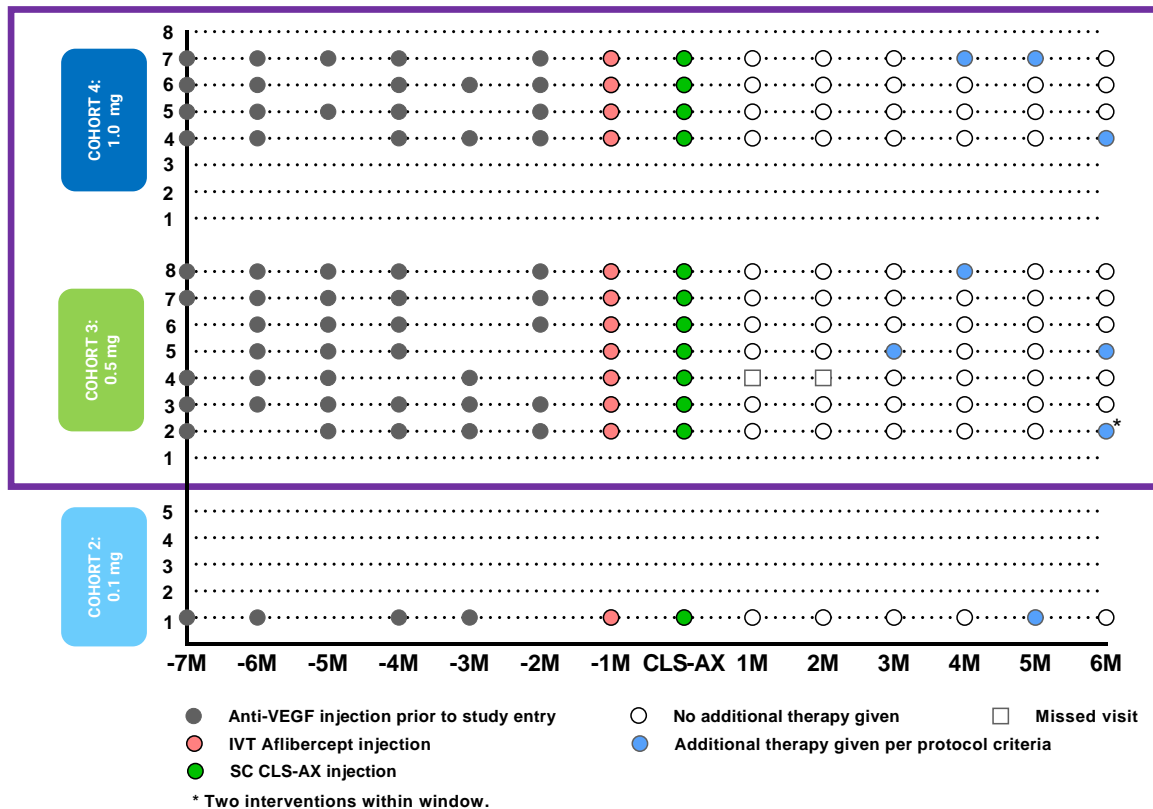
Extension Study (6 Month Data): Prior Anti-VEGF Therapies and All Additional Therapies



DURABILITY
Cohorts 3 & 4

No Additional Therapy
 ≥ 3 Months: 11/12 (92%)
 ≥ 4 Months: 10/12 (83%)
 ≥ 6 Months: 8/12 (67%)
 > 6 Months: 6/12 (50%)

Extension Study (6 Month Data): Prior Anti-VEGF Therapies and Additional Therapies Per Protocol Criteria



DURABILITY

Cohorts 3 & 4

No Additional Therapy
 ≥ 3 Months: 11/11 (100%)
 ≥ 4 Months: 10/11 (91%)
 ≥ 6 Months: 8/11 (73%)
 > 6 Months: 6/11 (55%)

Extension Study (6 Month): CLS-AX Demonstrated Reduction of Treatment Burden Across Cohorts

Observed Reduction in Treatment Burden All Therapies

Cohort	Number of Participants	Avg Monthly Injections Before CLS-AX Administration	Avg Monthly Injections After CLS-AX Administration	% Reduction
4	5	0.87	0.20	77.0
3	7	0.81	0.12	85.2
2	2	0.83	0.17	79.5

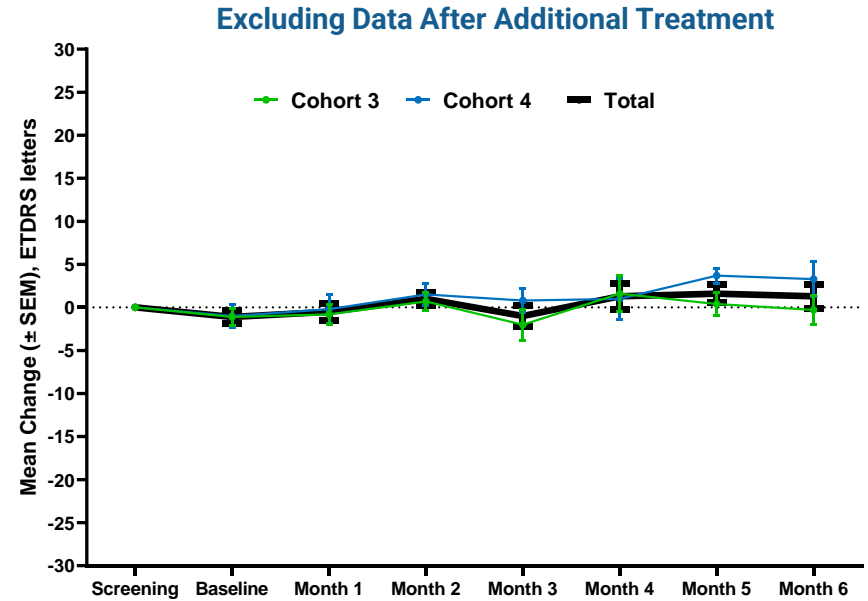
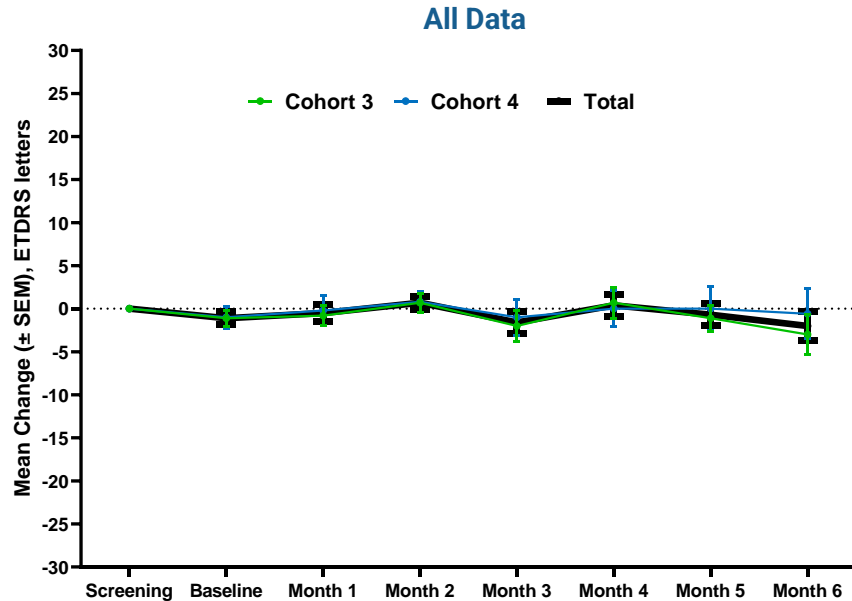
Observed Reduction in Treatment Burden Therapies Per Protocol Criteria

Cohort	Number of Participants	Avg Monthly Injections Before CLS-AX Administration	Avg Monthly Injections After CLS-AX Administration	% Reduction
4	4	0.83	0.13	84.3
3	7	0.81	0.12	85.2
2	1	0.67	0.17	74.6

77 – 85% Reduction in Treatment Burden in Cohorts 3 and 4

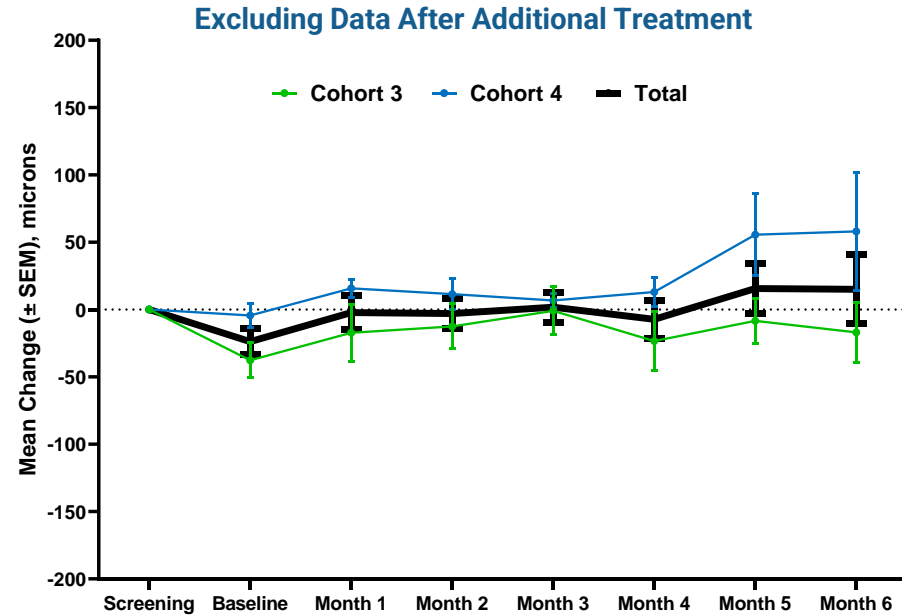
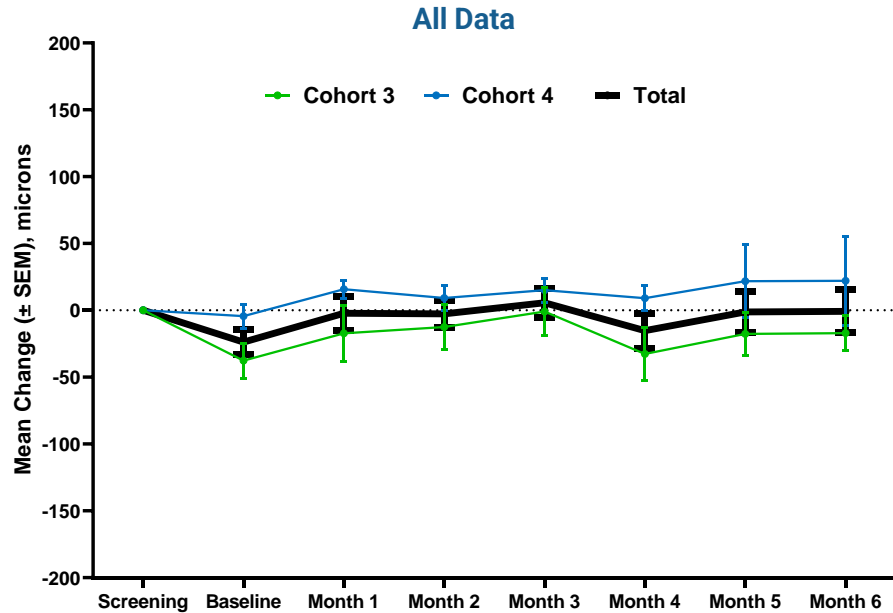
Extension Study (6 Month): Stable Visual Acuity

Mean Best Corrected Visual Acuity Letter Score, Change from Screening



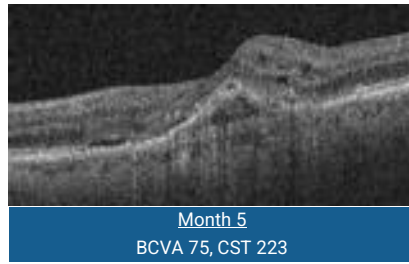
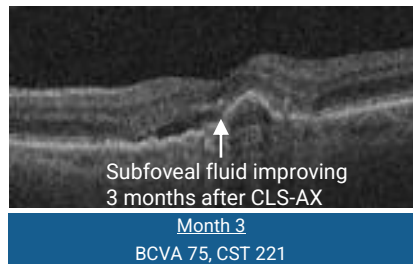
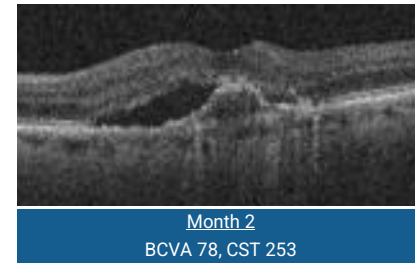
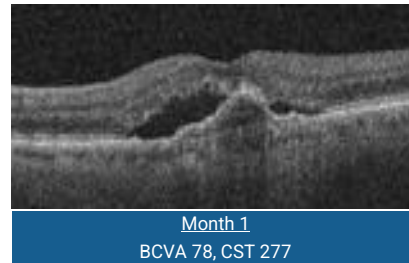
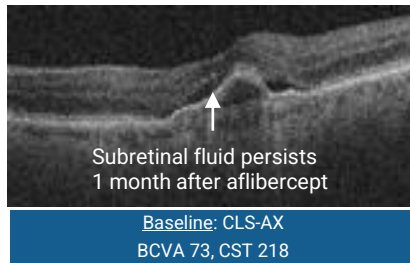
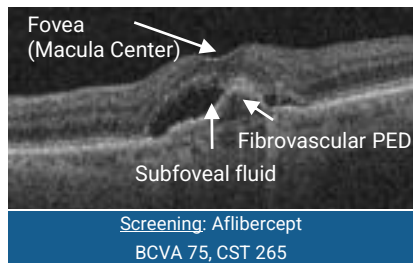
Extension Study (6 Month): Stable Central Subfield Thickness

Mean Central Subfield Thickness, Change from Screening



6 Month Case Study: A Biological Effect Following CLS-AX in Anti-VEGF Sub-responder

Cohort 3, Subject 2: 89 prior anti-VEGF injections with persistent subfoveal fluid 1 month after aflibercept at screen
Subretinal fluid gradually resolves through 4 months after CLS-AX with stable BCVA and improved CST



CLS-AX in Suprachoroidal Space Demonstrates Promising Safety Data, Durability and Biologic Effect in Anti-VEGF Treatment Experienced Sub-responders

	OASIS Results	Potential Competitive Advantages*
Safety Data (All Cohorts)	Excellent Safety Profile at all doses and timepoints <ul style="list-style-type: none"> No SAEs, No TEAEs related to study treatment No dose limiting toxicities No AEs related to inflammation, vasculitis or vascular occlusion No vitreous “floaters” or dispersion of CLS-AX into the vitreous No retinal detachments or endophthalmitis No AEs related to intraocular pressure 	<ul style="list-style-type: none"> As a well-characterized small molecule, less risk for inflammation than a novel biologic agent No need for an operating room setting No observed incidents of drug migration or vitreous “floaters” or haze in clinical trials, to date SCS injection procedure commercially accepted by retinal physicians following launch of XIPIRE®
Durability (Cohorts 3&4)	In Extension Study (N=12): <ul style="list-style-type: none"> ≥77% reduction in treatment burden Patients not requiring additional therapy: <ul style="list-style-type: none"> ≥ 3 Months: 11/12 (92%) ≥ 4 Months: 10/12 (83%) ≥ 6 Months: 8/12 (67%) > 6 Months: 6/12 (50%) 	<ul style="list-style-type: none"> CLS-AX showed preliminary signs of durability favorably comparing to other current and investigational intravitreally injected biologic agents Based on extension data at higher doses, CLS-AX suprachoroidal suspension demonstrated it may have durability of effect that favorably compares to other extended release TKI formulations
Biologic Effect (Cohorts 3&4)	CLS-AX showed signs of biologic effect: <ul style="list-style-type: none"> Stable mean BCVA Stable mean CST On OCT, anatomical signs of TKI biologic effect were observed in anti-VEGF treatment-experienced sub-responders 	<ul style="list-style-type: none"> The most potent TKI in nAMD trials, differentiated from focused VEGF-A blockade Targeted high levels to affected choroid-retina may further leverage efficacy, particularly in anti-VEGF sub-responders

ODYSSEY
CLS-AX
Phase 2b
Clinical Trial



ODYSSEY Phase 2b Trial in Treatment-Naïve Wet AMD Participants

Randomized, Double-Masked, CLS-AX Maintenance vs Faricimab Maintenance



Trial Objectives:

Stable visual acuity with reduced treatment burden/better durability



Number of Participants:

Total of 110 patients
(55 in each arm)

- **Key inclusion criteria:**
 - Treatment naïve wet AMD participants
 - Subfoveal CNV secondary to wet AMD
 - Best Corrected Visual Acuity (BCVA) of 78–24 letters*
- **Primary endpoint:** Mean change in BCVA
- **Key secondary endpoints:**
 - Mean change in Central Subfield Thickness (CST)
 - Treatment burden reduction as measured by total anti-VEGF injections over trial duration
- **Monthly disease activity assessments:** Beginning 2 months after last faricimab loading dose to determine if retreatment is needed
- **Retreatment criteria:** Decrease in BCVA, increase in CST, or new macular hemorrhage (per faricimab Phase 3 trial retreatment criteria#)

* Inclusive (20/32–20/320 approximate Snellen equivalent)

Increase ≥ 75 μm in CST compared with the lowest CST value recorded at either of the previous 2 scheduled visits, or
Increase > 50 μm in CST compared with the average CST value over the previous 2 scheduled visits, or
Decrease ≥ 5 letters in BCVA compared with the average BCVA value over the previous 2 scheduled visits, owing to nAMD disease activity (as determined by the Investigator), or
Decrease ≥ 10 letters in BCVA compared with the highest BCVA value recorded at either of the previous 2 scheduled visits, owing to nAMD disease activity (as determined by the Investigator), or
Presence of new macular hemorrhage (as determined by the Investigator), owing to nAMD disease activity.

ODYSSEY Wet AMD Phase 2b Trial – Clinical Rationale

Potential to Demonstrate Better Durability and Reduced Treatment Burden

CLS-AX

Mechanism of Action: Pan-VEGF receptor inhibitor delivered by SCS Microinjector®

OASIS Phase 1/2a clinical trial data in treatment-experienced anti-VEGF sub-responders:

- 83% went \geq 4 months without additional treatment
- 67% went \geq 6 months without additional treatment
- 50% did not require additional treatment for more than 6 months

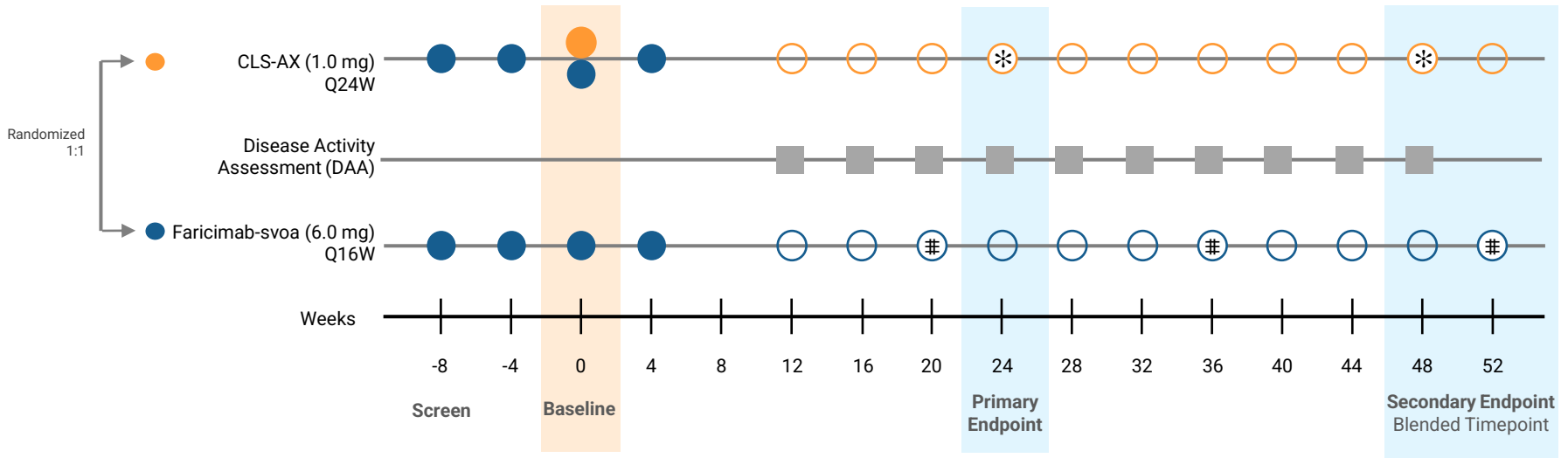
Faricimab

Mechanism of Action: VEGF & angiopoietin 2 (Ang-2) inhibitor delivered by intravitreal injection

Phase 3 clinical trial data in treatment naïve participants¹:

- 55% required additional treatment \leq 3 months after four monthly loading doses
 - 2 months after loading doses: 22% required retreatment
 - 3 months after loading doses: 33% required retreatment

ODYSSEY Phase 2b Trial Design



- **Both Arms:** 4 monthly faricimab loading doses; then monthly disease activity assessments (DAA) with retreatment if required per protocol.
- * **CLS-AX Arm:** Participants are required to be dosed with CLS-AX at least every 6 months following the last CLS-AX dose. Participants may be dosed sooner than 6 months with CLS-AX if retreatment criteria is met during a DAA.
- # **Faricimab Arm:** Participants are required to be dosed with faricimab at least every 4 months (per label). Participants may be dosed sooner with faricimab if retreatment criteria is met during a DAA. If participants are retreated earlier than 4 months, they will continue to receive further doses of faricimab at that dosing interval for the remainder of the study (per label).

ODYSSEY Wet AMD Phase 2b Trial Summary

Comparator

- VABYSMO® (faricimab-svoa) is the most recently approved product for wAMD
- Selected based on KOL input anticipating VABYSMO could become the future branded standard of care

Treatment-Naïve Participants

- More likely to respond to treatment and show similar visual stability to standard of care than treatment resistant participants
- Same population as faricimab Phase 3 trials

Maintenance Dosing Regimen

- Designed to demonstrate reduced treatment burden and better durability of CLS-AX versus on-label faricimab dosing; Same disease activity assessment design as faricimab Phase 3 trials
- CLS-AX has potential for 2-3x/year maintenance dosing compared to on-label maintenance dosing for approved drugs: LUCENTIS®: 12x/year, EYLEA®: 6x/year, VABYSMO®: up to 6x/year

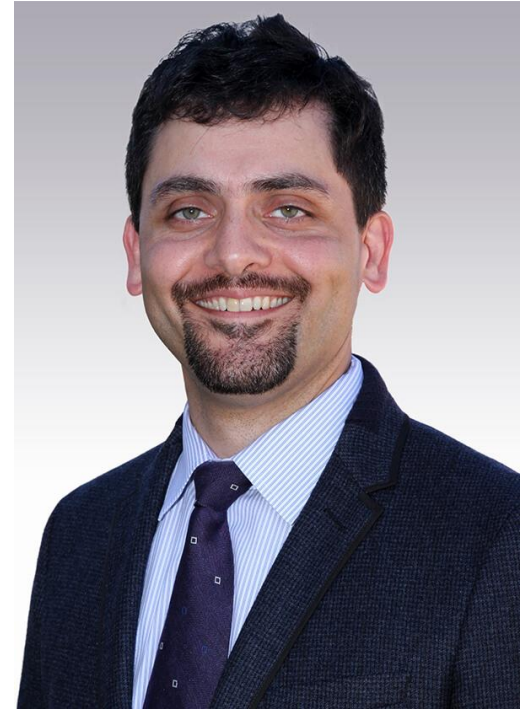
Trial Size and Timeline

- 6-month primary endpoint and 12-month secondary endpoints expected to produce comparable visual acuity results with lower treatment burden
- Balanced to meet objectives, recruit in timely manner and to produce meaningful results in a reasonable time, with anticipated data readout in mid-2024

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NASDAQ: CLSD



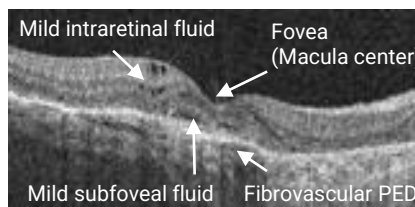
OASIS

Case Studies

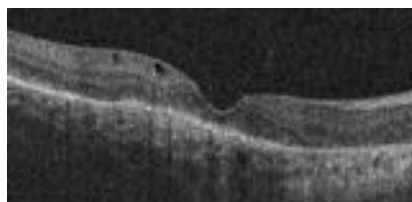


6 Month Case Study: Durable Stability After CLS-AX

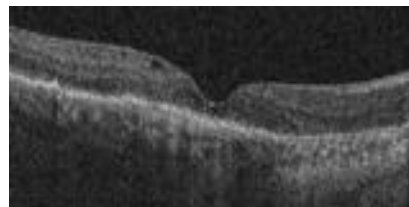
Cohort 3, Subject 3: 65 prior anti-VEGF injections with PED, mild subfoveal and intraretinal fluid at screen
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



Screening: Aflibercept
BCVA 37, CST 228



Baseline: CLS-AX
BCVA 37, CST 181



Month 1
BCVA 39, CST 175



Month 2
BCVA 35, CST 175



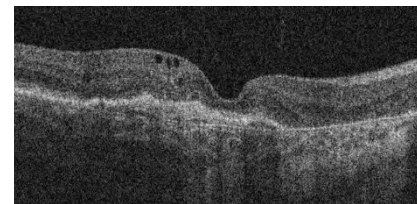
Month 3
BCVA 36, CST 205



Month 4
BCVA 40, CST 190



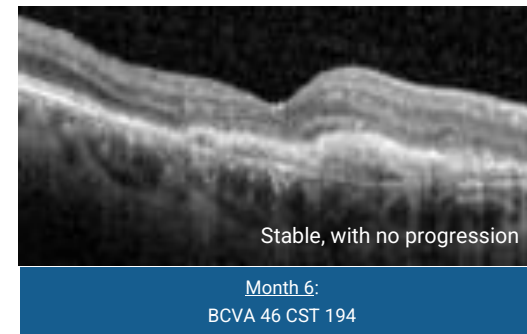
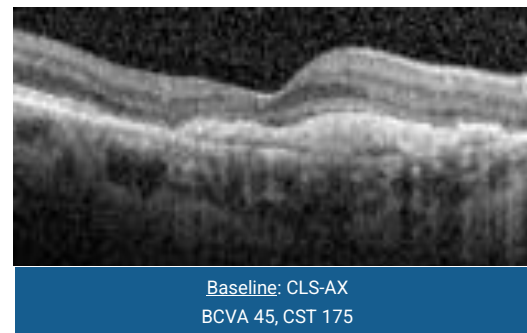
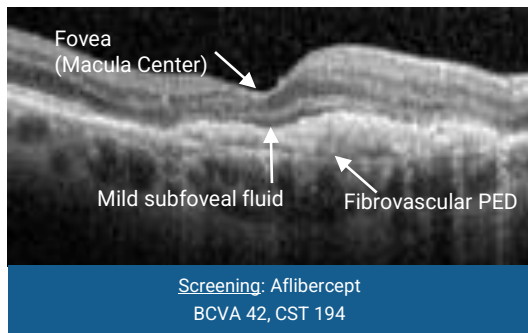
Month 5
BCVA 38, CST 200



Month 6
BCVA 38, CST 184

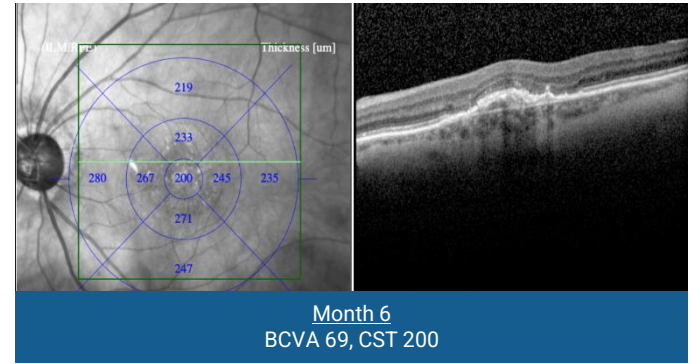
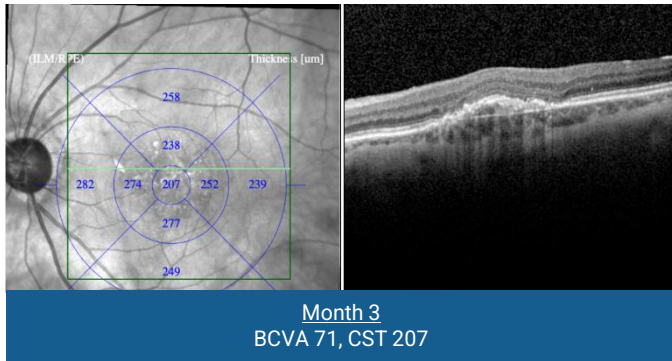
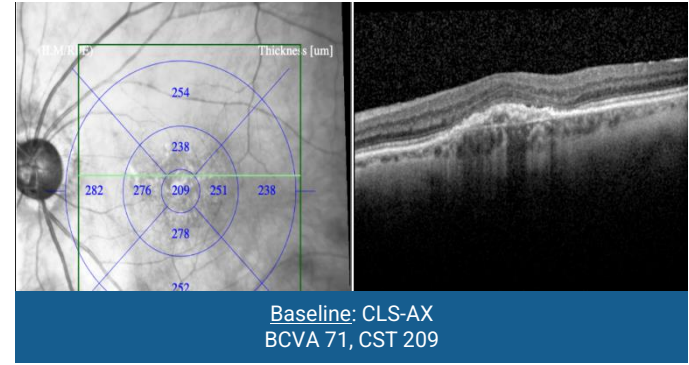
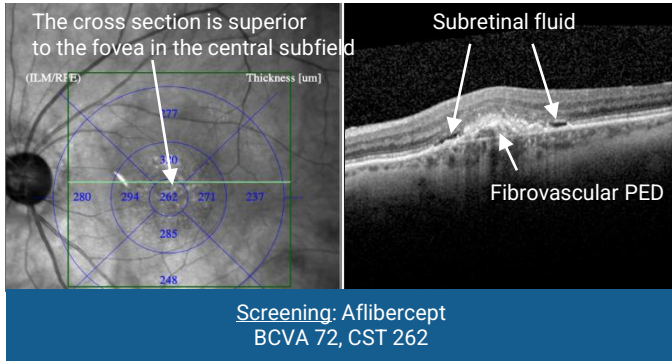
6 Month Case Study: Durable Stability After CLS-AX

Cohort 3, Subject 4: 14 prior anti-VEGF injections with mild subfoveal fluid at screen
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



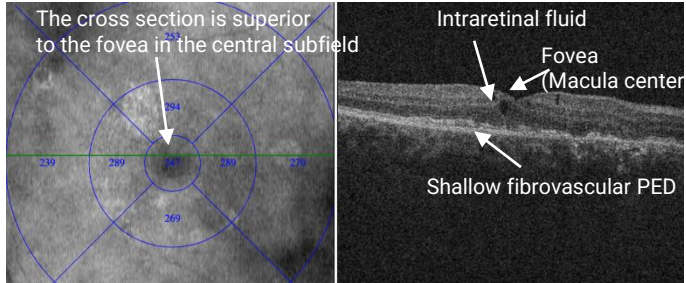
6 Month Case Study: Durable Stability After CLS-AX

Cohort 3, Subject 6: 49 prior anti-VEGF injections with persistent subretinal fluid in superior central subfield
 Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy

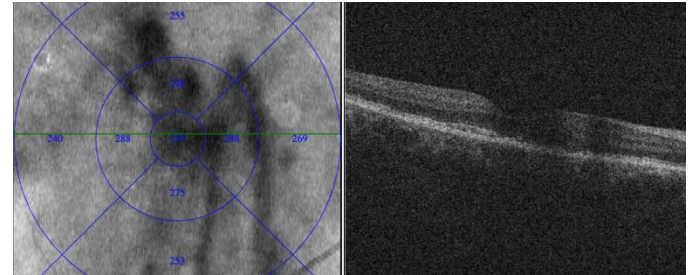


6 Month Case Study: Durable Stability After CLS-AX

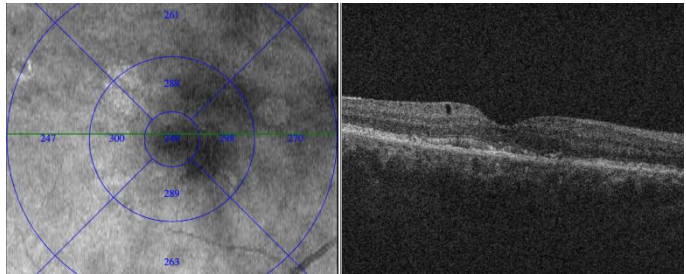
Cohort 4, Subject 5: 29 prior anti-VEGF injections with persistent PED and intraretinal fluid in superior central subfield
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



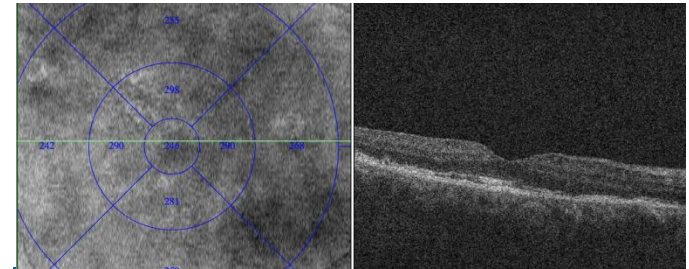
Screening: Aflibercept
BCVA 70, CST 244



Baseline: CLS-AX
BCVA 70, CST 234



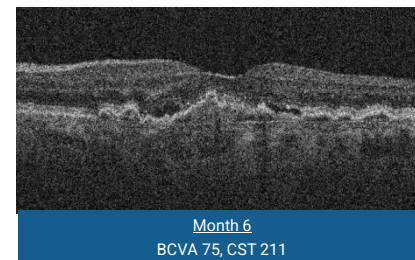
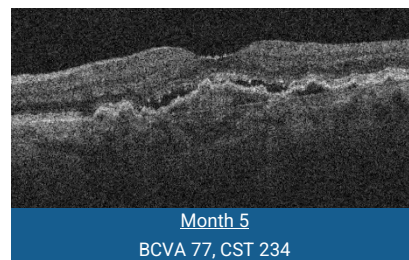
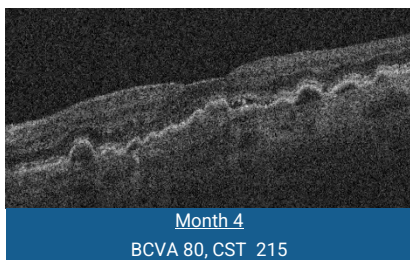
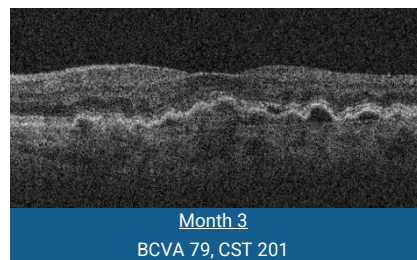
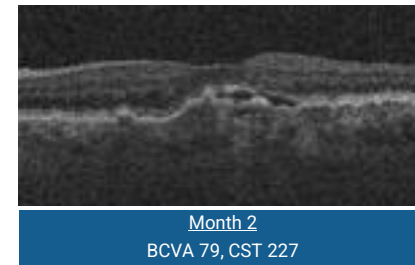
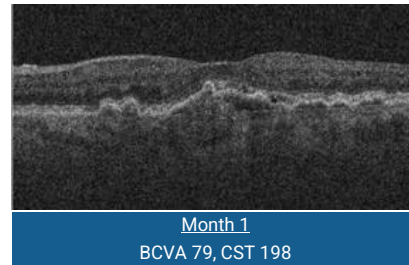
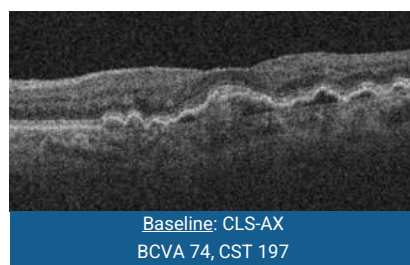
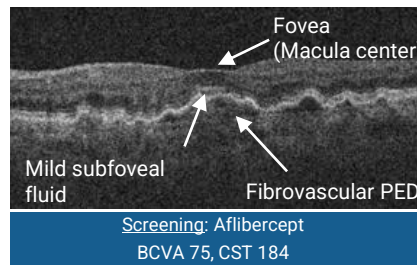
Month 3
BCVA 69, CST 249



Month 6
BCVA 73, CST 246

6 Month Case Study: Durable Stability After CLS-AX

Cohort 4, Subject 6: 29 prior anti-VEGF injections with PED and mild subfoveal at screen
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



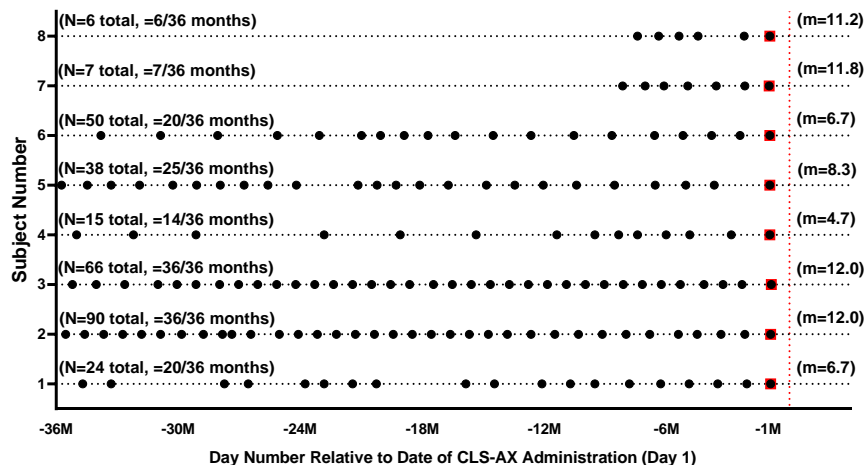
OASIS

Individual Patient
Data



Anti-VEGF Treatments up to 3 Years Prior to Baseline CLS-AX Administration

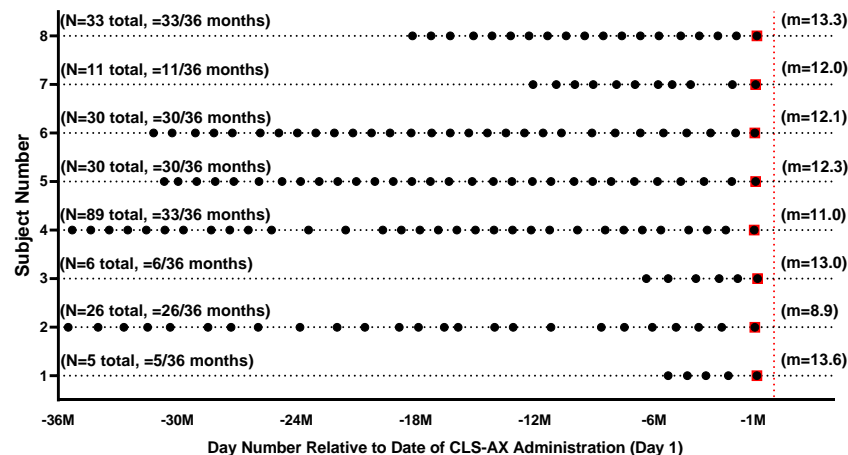
COHORT 3: 0.5 mg



● Prior nAMD Treatment ■ IVT Aflibercept (Screening, Visit 1)

(N=) Total number of nAMD treatments reported prior to CLS-AX (Day 1), within 36 months
 (m=) Annualized number of injections in the past 36 months defined as (total number of injections in 36 months prior to CLS-AX (Day 1)) / (minimum(3, (Duration between first injection and Day 1)/365.25)).

COHORT 4: 1.0 mg



● Prior nAMD Treatment ■ IVT Aflibercept (Screening, Visit 1)

(N=) Total number of nAMD treatments reported prior to CLS-AX (Day 1), within 36 months
 (m=) Annualized number of injections in the past 36 months defined as (total number of injections in 36 months prior to CLS-AX (Day 1)) / minimum(3, (duration between first injection and Day 1)/365.25)).

Extension Study: Reason for Use of Additional Therapies (in Months 4, 5, 6)

COHORT	SUBJECT	ADDITIONAL THERAPY VISIT	REASON FOR ADDITIONAL THERAPY
COHORT 2: 0.10 mg (N=2)	1	5 months post CLS-AX	Macular hemorrhage
COHORT 3: 0.5 mg (N=7)	2	6 months post CLS-AX *	BCVA with exudation
	5	6 months post CLS-AX	CST
	8	4 months post CLS-AX	CST
COHORT 4: 1.0 mg (N=5)	3	5 months post CLS-AX	CST (not verified by reading center)
	4	6 months post CLS-AX	CST
	7	4 and 5 months post CLS-AX	BCVA with exudation

* Two interventions within window

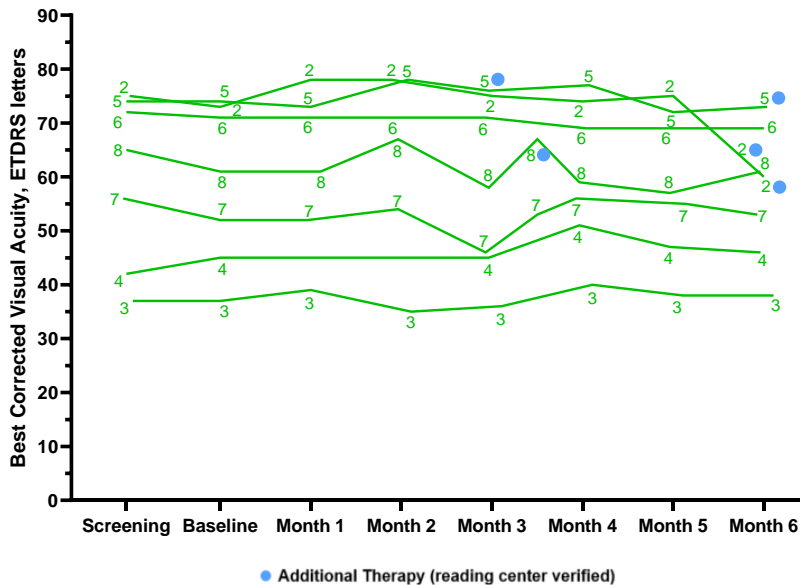
Red = not treated per protocol defined criteria

Assessment for additional treatment with aflibercept:

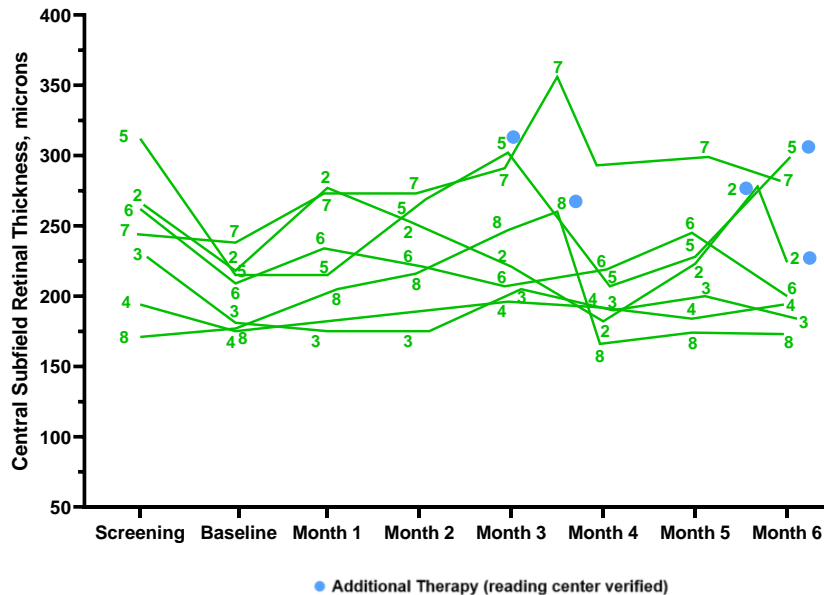
Decrease from best measurement of ≥ 10 letters in BCVA with exudation; Increase in CST > 75 microns; A vision-threatening hemorrhage

Cohort 3 Extension Study: Stable Best Corrected Visual Acuity and Central Subfield Thickness Beyond 3 Months

COHORT 3 (0.5 mg): BCVA

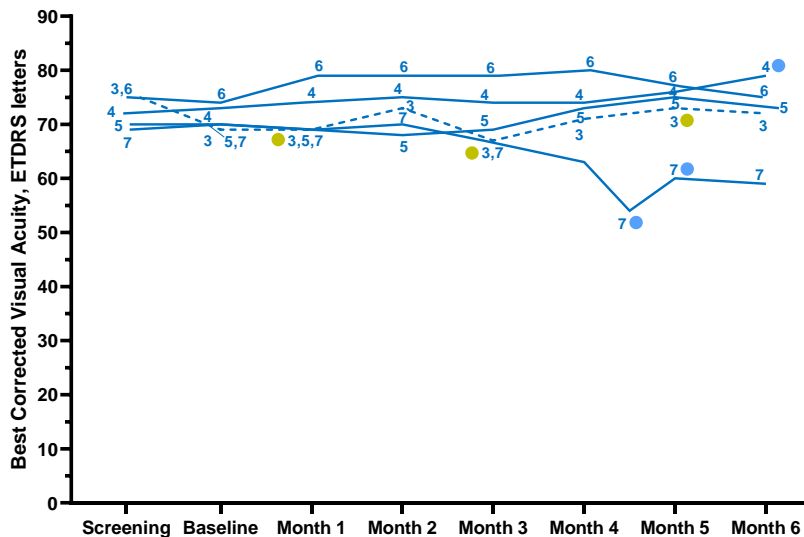


COHORT 3 (0.5 mg): CST

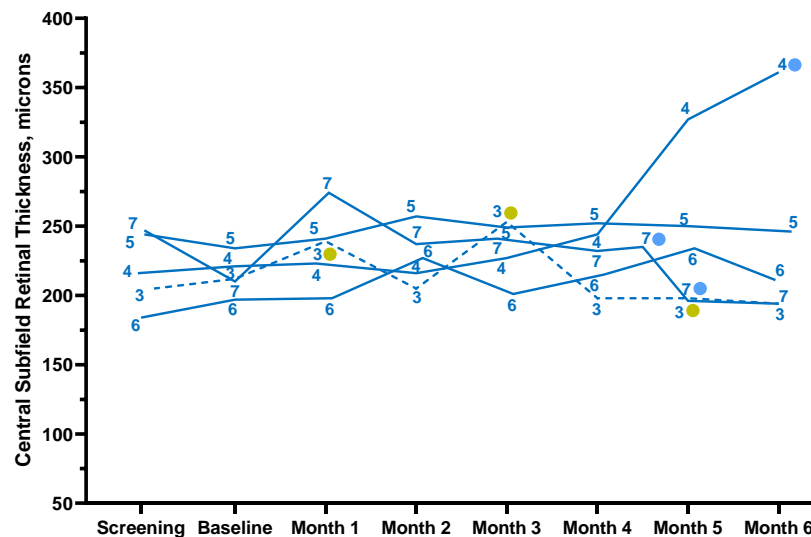


Cohort 4 Extension Study: Stable Best Corrected Visual Acuity and Central Subfield Thickness Beyond 3 Months

COHORT 4 (1.0 mg): BCVA



COHORT 4 (1.0 mg): CST



● Additional Therapy (reading center verified) ● Additional Therapy (not reading center verified) ● Additional Therapy (reading center verified) ● Additional Therapy (not reading center verified)

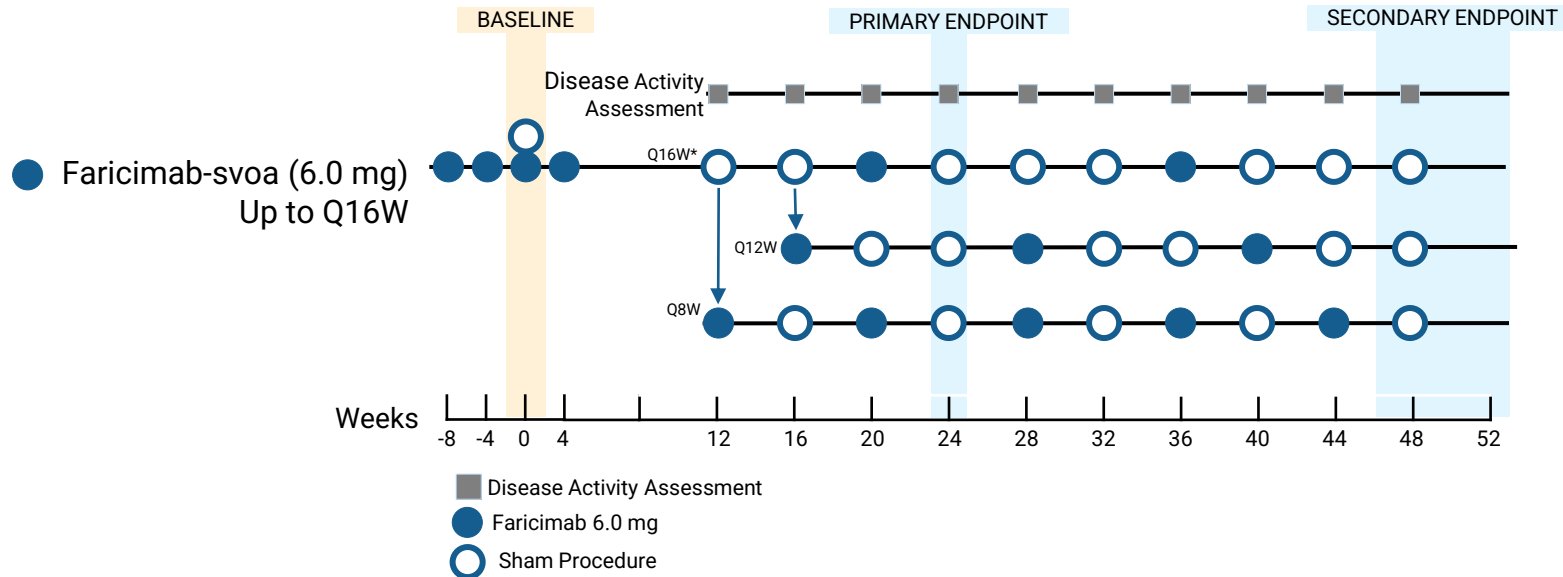
Dotted line = patient received additional therapy not per protocol (not reading center verified or physician discretion)

OASIS

Appendix



ODYSSEY Phase 2b Trial: Control Arm Dosing Per Label





CLEARSIDE BIOMEDICAL

NASDAQ: CLSD

