UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 2, 2023

Clearside Biomedical, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37783**	**45-2437375**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

900 North Point Parkway, Suite 200
Alpharetta, GA 30005
(Address of principal executive offices, including zip code)

(678) 270-3631
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CLSD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 2, 2023, Clearside Biomedical, Inc. (the "***Company***") issued a press release which included the following disclosure:

"As of December 31, 2022, we had approximately $48.3 million of cash and cash equivalents. This amount is an unaudited and preliminary estimate that (i) represents the most current information available to management as of the date of this prospectus supplement, (ii) is subject to completion of financial closing and auditing procedures that could result in significant changes to the estimated amounts and (iii) does not present all information necessary for an understanding of our financial condition as of, and our results of operations for the year ended, December 31, 2022. Accordingly, you should not place undue reliance on this preliminary estimate."

Item 7.01 Regulation FD Disclosure.

The Company will host a conference call on February 2, 2023 to discuss positive results from the extension study of the Company's OASIS Phase 1/2a clinical trial of CLS-AX in wet AMD. The information regarding the conference call is included in the press release described below. A copy of the presentation to be presented on the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K. The presentation may be accessed on the Company's website under the "Investors" section.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

Item 8.01 Other Events.

On February 2, 2023, the Company issued a press release announcing positive results from the extension study of the Company's OASIS Phase 1/2a clinical trial of CLS-AX in wet AMD. A copy of the press releases is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Caution Concerning Forward Looking Statements

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21 E of the Exchange Act. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. These forward-looking statements include statements clinical development of the Company's product candidates, expectations regarding future clinical trials, the preliminary financial results as of December 31, 2022 and future expectations and plans and prospects for the Company. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including the uncertainties related to market conditions and uncertainties inherent in the initiation of future clinical trials. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company's business are described in additional detail in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "***Commission***") on March 11, 2022, the Company's Quarterly Report on Form 10-Q filed with the Commission on November 9, 2022, and in the Company's other Periodic and Current Reports filed with the Commission. The Company is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Presentation, dated February 2, 2023
99.2	Press Release, dated February 2, 2023 titled "Clearside Biomedical Announces Positive Results from OASIS Extension Study with Suprachoroidal CLS-AX (axitinib injectable suspension) in Wet AMD"
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 2, 2023

CLEARSIDE BIOMEDICAL, INC.

By: /s/ Charles A. Deignan
Name: Charles A. Deignan
Title: Chief Financial Officer

Exhibit 99.1

CLEARSIDE BIOMEDICAL

OASIS

OASIS Phase 1/2a Clinical Trial

6-Month Extension Study Results

February 2, 2023

Forward-Looking Statements

This presentation contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" or the negative of these terms and other similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Clearside Biomedical, Inc.'s views as of the date of this presentation about future events and are subject to risks, uncertainties, assumptions, and changes in circumstances that may cause Clearside's actual results, performance, or achievements to differ significantly from those expressed or implied in any forward-looking statement. Although Clearside believes that the expectations reflected in the forward-looking statements are reasonable, new risks and uncertainties may emerge from time to time, and Clearside cannot guarantee future events, results, performance, or achievements. Some of the key factors that could cause actual results to differ from Clearside's expectations include its plans to develop and potentially commercialize its product candidates; adverse differences between preliminary or interim data and final data; Clearside's planned clinical trials and preclinical studies for its product candidates; the timing of and Clearside's ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Clearside's product candidates; the clinical utility and market acceptance of Clearside's product candidates; Clearside's commercialization, marketing and manufacturing capabilities and strategy; Clearside's intellectual property position; Clearside's ability to expand its pipeline; developments and projections relating to Clearside's competitors and its industry; the impact of government laws and regulations; the impact of public health epidemics affecting countries or regions in which Clearside has operations or does business, such as the COVID-19 pandemic; the timing and anticipated results of Clearside's preclinical studies and clinical trials and the risk that the results of Clearside's preclinical studies and clinical trials may not be predictive of future results in connection with future studies or clinical trials and may not support further development and marketing approval; findings from investigational review boards at clinical trial sites and publication review bodies; Clearside's estimates regarding future revenue, expenses, capital requirements and need for additional financing; and Clearside's ability to identify additional product candidates with significant commercial potential that are consistent with its commercial objectives. For further information regarding these risks, uncertainties and other factors you should read the "Risk Factors" section of Clearside's Annual Report on Form 10-K for the year ended December 30, 2021, filed with the SEC on March 11, 2022, Clearside's Form 10-Q for the quarter ended September 30, 2022, filed with the SEC on November 9, 2022, and Clearside's other Periodic Reports filed with the SEC. Clearside expressly disclaims any obligation to update or revise the information herein, including the forward-looking statements, except as required by law. This presentation also contains estimates and other statistical data made by independent parties and by Clearside relating to market size and growth and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of Clearside's future performance and the future performance of the markets in which Clearside operates are necessarily subject to a high degree of uncertainty and risk.

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

- First FDA Approved Product: XIPERE®
- Proprietary CLS-AX Phase 1/2 data in Wet AMD shows significant reduction in treatment burden and demonstrated a strong duration profile
- Proprietary Access to the Suprachoroidal Space (SCS®)
- Internal Research & Development Pipeline
- External Collaborations for Pipeline Expansion

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:
  - ≥72% reduction in treatment burden
- In Extension Study, to 6 months:
  - ≥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

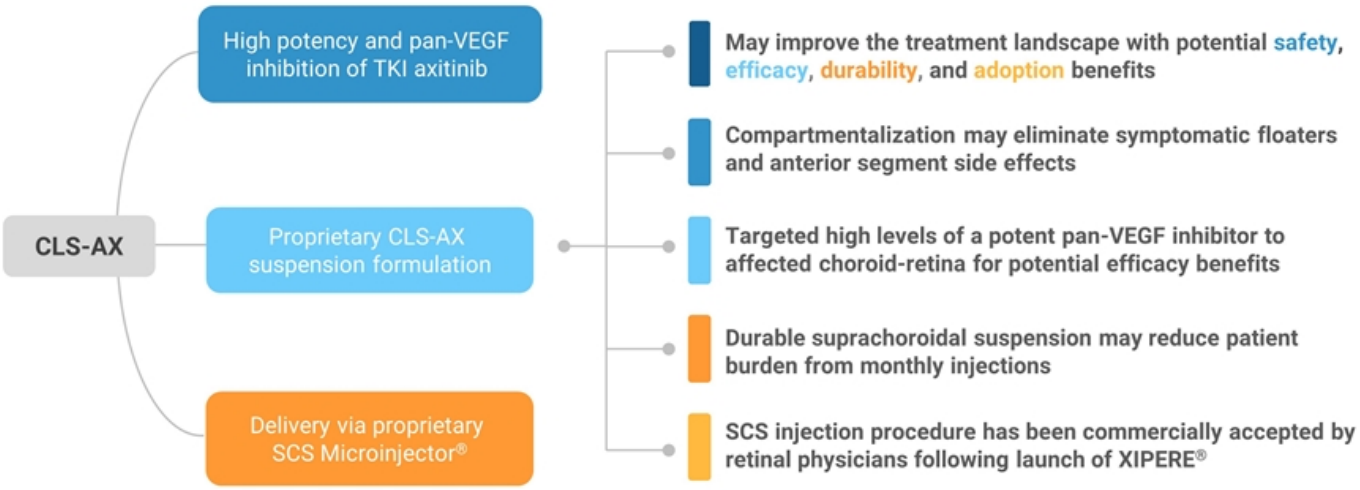
- Expect to initiate Phase 2b clinical trial in Q1 2023 with primary endpoint readout anticipated in mid-2024

Source: Clearside data on file.


CLS-AX
(axitinib injectable suspension)
for Suprachoroidal Injection

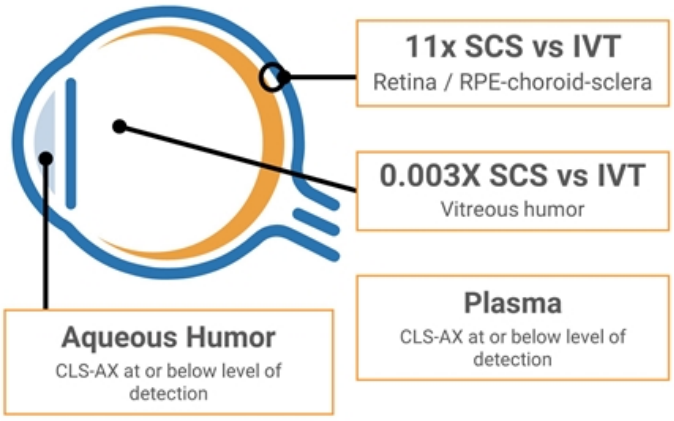
CLS-AX (axitinib injectable suspension) for Suprachoroidal Use

Leveraging a Highly Potent Pan-VEGF Inhibitor with Suprachoroidal Delivery



Axitinib is a tyrosine kinase inhibitor (TKI) | XIPERE® (triamcinolone acetonide injectable suspension), for suprachoroidal use has received U.S. FDA Approval. Please see Important Safety Information for XIPERE® in the Full Prescribing Information: https://www.bauschhealth.com/Portals/25/Pdf/PI/XIPERE-PI.pdf. | Source: Viral S. Kansara, Leroy W. Muya, Thomas A. Ciulla; Evaluation of Long-Lasting Potential of Suprachoroidal Axitinib Suspension Via Ocular and Systemic Disposition in Rabbits. *Trans. Vis. Sci. Tech.* 2021;10(7):19.

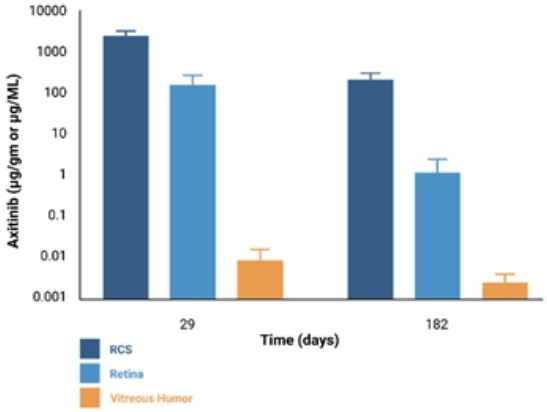
CLS-AX Injected Suprachoroidally Provides Targeted Delivery Relative to Intravitreal Injection at Same Dose



Rabbit Model Values: area under the curve ratios, SCS / IVT
SCS : 1 mg/eye, 100 µL. | IVT: 1 mg/eye, 25 µL
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)

Sources: Viral S. Kansara, Leroy W. Muya, Thomas A. Ciulla; Evaluation of Long-Lasting Potential of Suprachoroidal Axitinib Suspension Via Ocular and Systemic Disposition in Rabbits. *Trans. Vis. Sci. Tech.* 2021;10(7):19.
Abbreviations: SCS: Suprachoroidal Space | IVT: Intravitreal Injection | PK: Pharmacokinetic | RPE: Retinal pigment epithelium I RCS: RPE, Choroid, Sclera

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

CLEARSIDE BIOMEDICAL

Note: aflibercept is dosed via intravitreal injection (IVT); CLS-AX is dosed via suprachoroidal injection | clinicaltrials.gov NCT# 04626128
Active Disease definition: Active subfoveal choroidal neovascularization (CNV) secondary to AMD in the study eye confirmed by an independent reading center as leakage from a subfoveal CNV on fluorescein angiography and intra-retinal or sub-retinal fluid on OCT central subfield)
Cohort 1 not offered extension trial

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

Core et at. Predominantly Persistent Intraretinal Fluid in the Comparison of Age-related Macular Degeneration Treatments Trials. Ophthalmol Retina. 2022 Sep;6(9):771-785. | Waldstein et al. Morphology and visual acuity in aflibercept and ranibizumab therapy for neovascular age-related macular degeneration in the VIEW trials. Ophthalmology 2016;123:1521-1529.
Active Disease definition: Active subfoveal choroidal neovascularization (CNV) secondary to AMD in the study eye confirmed by an independent reading center as leakage from a subfoveal CNV on fluorescein angiography and intra-retinal or sub-retinal fluid on OCT central subfield)

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)**

Source: Clearside data on file.

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)**

Source: Clearside data on file.
Cohort 2 data calculated with number of patients with available data. Cohorts 3 & 4 data calculated with number of participants.


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

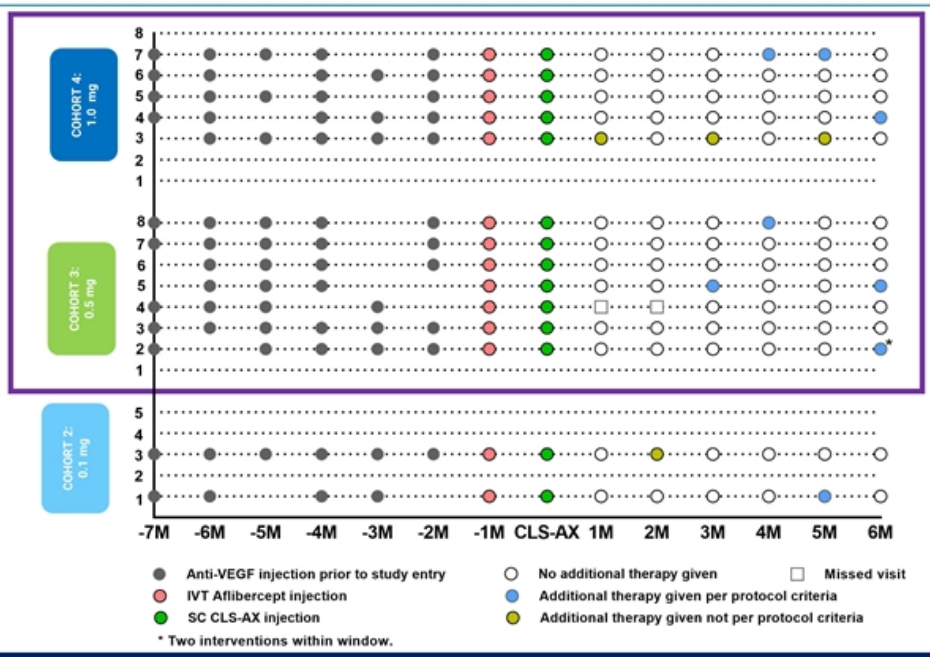
SAFETY DATA

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

Source: Clearside data on file.

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



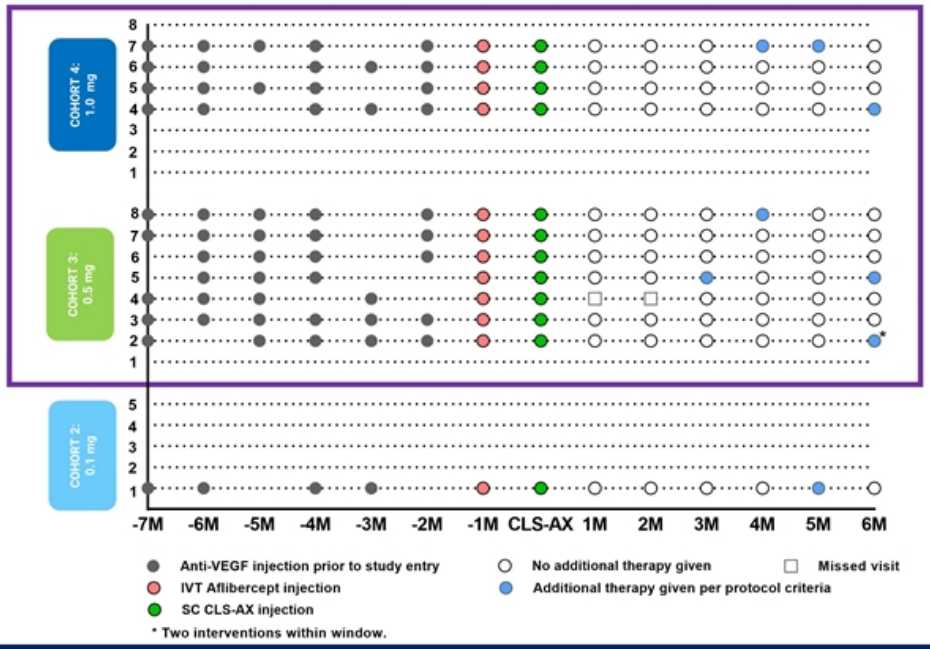
DURABILITY

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%)

Excludes patients whose first additional therapy was not per protocol-defined criteria.
Source: Clearside data on file.

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

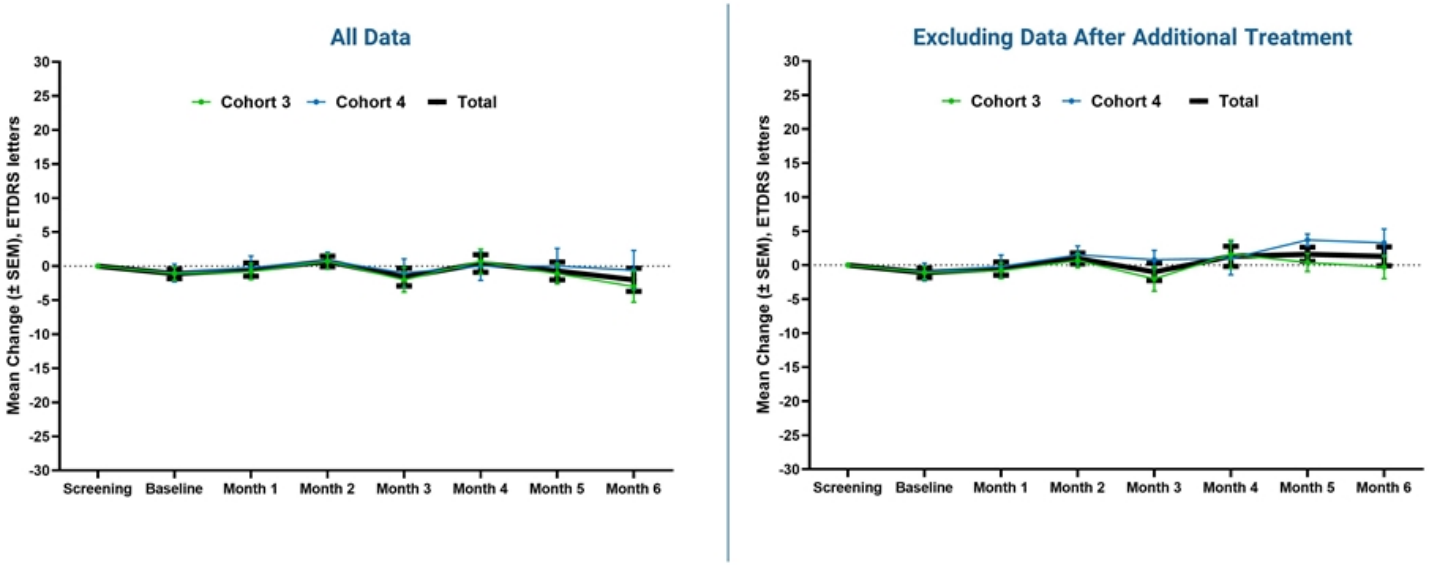
77 – 85% Reduction in Treatment Burden in Cohorts 3 and 4

CLEARSIDE BIOMEDICAL

Note: Average Monthly Injections Before CLS-AX Administration = # treatments six months prior/ 6.
Average Monthly Injections After CLS-AX Administration = # treatments / # months of follow-up.
% Reduction = Average of individual reductions calculated as (after – before) / before × 100%.
Source: Clearside data on file.

Extension Study (6 Month): Stable Visual Acuity

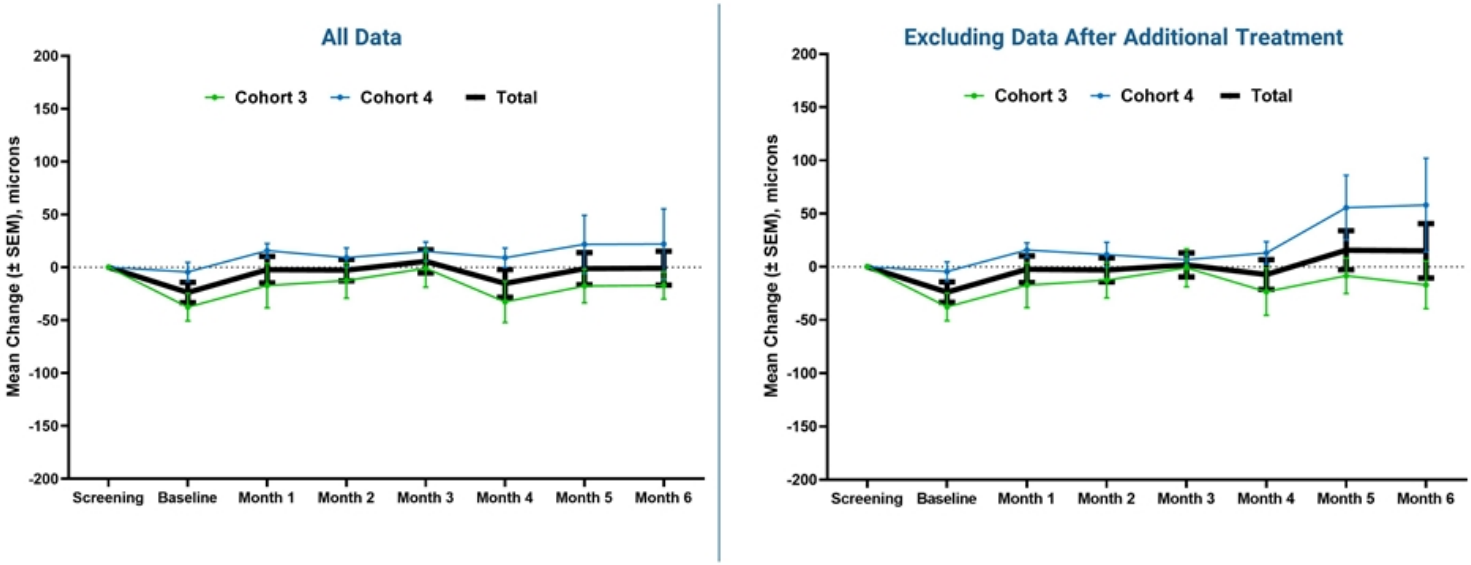
Mean Best Corrected Visual Acuity Letter Score, Change from Screening



Source: Clearside data on file.

Extension Study (6 Month): Stable Central Subfield Thickness

Mean Central Subfield Thickness, Change from Screening

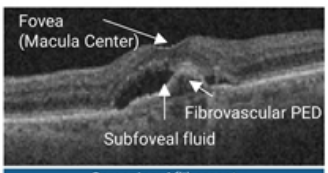


Source: Clearside data on file.

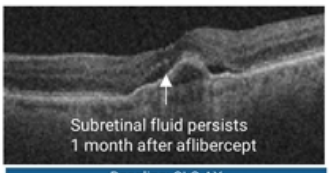
6 Month Case Study:
A Biological Effect Following CLS-AX in Anti-VEGF Sub-responder

Cohort 3, Subject 2: 89 prior anti-VEGF injections with persistent subfoveal fluid 1 month after aflibercept at screen

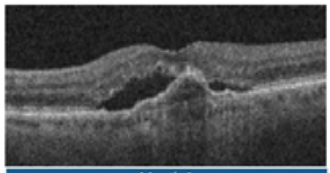
Subretinal fluid gradually resolves through 4 months after CLS-AX with stable BCVA and improved CST



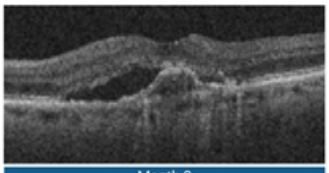
Screening: Aflibercept
BCVA 75, CST 265



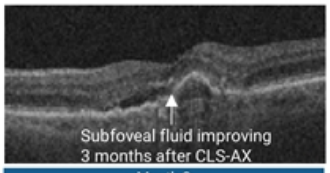
Baseline: CLS-AX
BCVA 73, CST 218



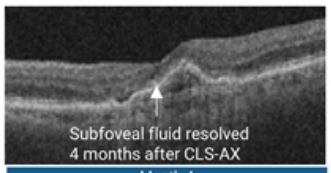
Month 1
BCVA 78, CST 277



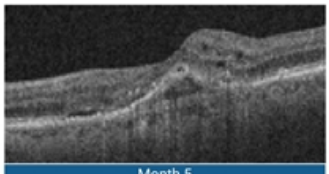
Month 2
BCVA 78, CST 253



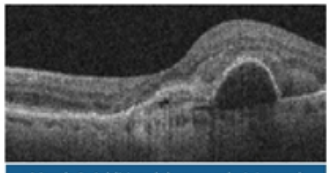
Month 3
BCVA 75, CST 221



Month 4
BCVA 74, CST 182



Month 5
BCVA 75, CST 223



Month 6: Additional therapy administered
BCVA 60, CST 224

Source: Clearside data on file. | Previous treatments prior to screening.

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** • 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	• 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 XIPERE®
Durability (Cohorts 3&4)	**In Extension Study (N=12):** • **≥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%)**	• 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:** • Stable mean BCVA • Stable mean CST • On OCT, anatomical signs of TKI biologic effect were observed in anti-VEGF treatment-experienced sub-responders	• 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

Source: Clearside data on file. | XIPERE® (triamcinolone acetonide injectable suspension), for suprachoroidal use received U.S. FDA Approval in October 2021. Please see Important Safety Information for XIPERE® in the Full Prescribing Information, 2022: https://www.bauschhealth.com/Portals/25/Pdf/PI/XIPERE-PI.pdf.
*CLS-AX has not been evaluated against other products in head-to-head clinical trials.


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#)

CLEARSIDE BIOMEDICAL

* 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 ≥ 4 months without additional treatment
- 67% went ≥ 6 months without additional treatment
- 50% did not require additional treatment for more than 6 months

Faricimab

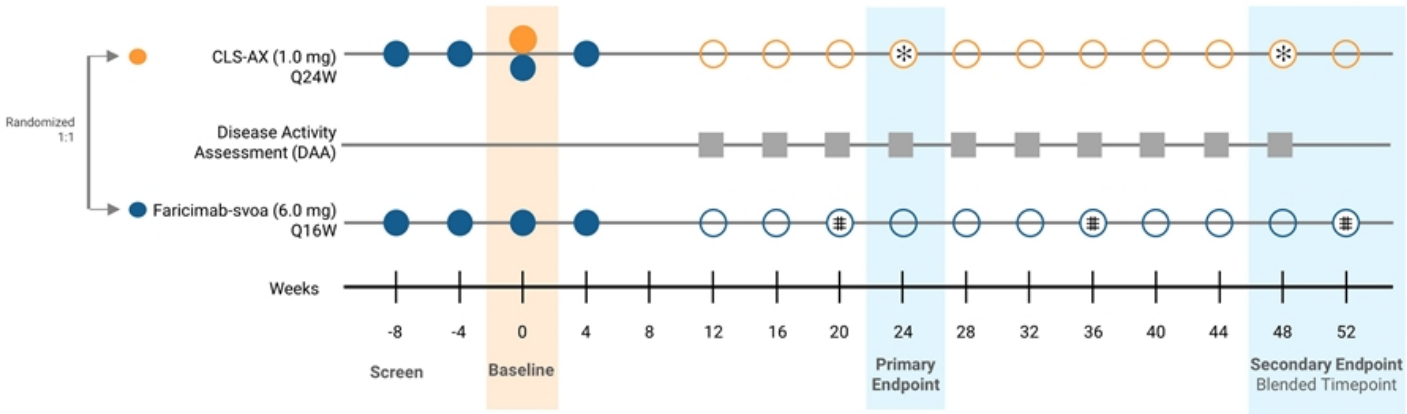
Mechanism of Action: VEGF & angiopoietin 2 (Ang-2) inhibitor delivered by intravitreal injection

Phase 3 clinical trial data in treatment naïve participants[1]:

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

[1]Refer to Prescribing Information for VABYSMO® (faricimab-svoa) injection, for intravitreal use.

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).**

Note: Proposed clinical trial design.

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

Mark R. Barakat, M.D.

Director of Retinal Research Institute,
Retinal Consultants of Arizona

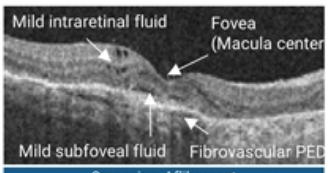
Clinical Assistant Professor of Ophthalmology,
University of Arizona College of Medicine - Phoenix


CLEARSIDE
BIOMEDICAL
NASDAQ: CLSD

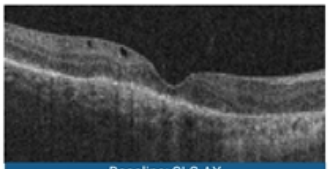

OASIS
Case Studies

6 Month Case Study: Durable Stability After CLS-AX

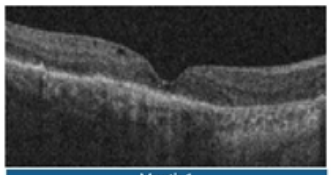
Cohort 3, Subject 3: 65 prior anti-VEGF injections with PED, mild subfoveal and intraretinal fluid at screen
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



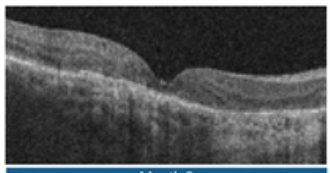
Screening: Aflibercept
BCVA 37, CST 228



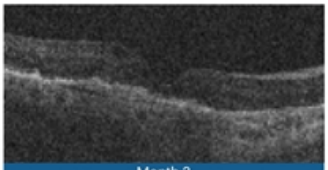
Baseline: CLS-AX
BCVA 37, CST 181



Month 1
BCVA 39, CST 175

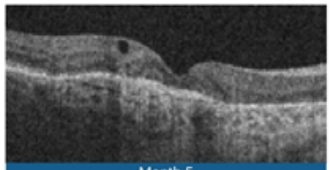


Month 2
BCVA 35, CST 175

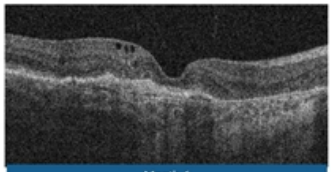


Month 3
BCVA 36, CST 205

Month 4
BCVA 40, CST 190



Month 5
BCVA 38 , CST 200

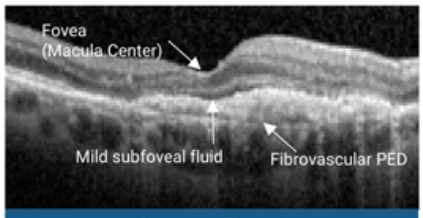


Month 6
BCVA 38, CST 184

Source: Clearside data on file. | Previous treatments prior to screening.

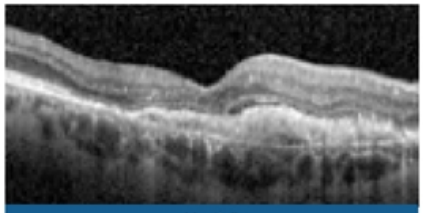
6 Month Case Study: Durable Stability After CLS-AX

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

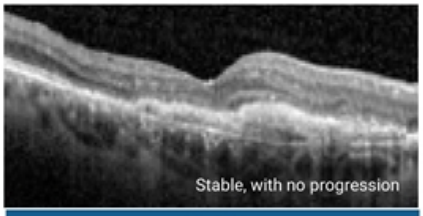


Screening: Aflibercept
BCVA 42, CST 194

Baseline: CLS-AX
BCVA 45, CST 175



Month 3
BCVA 45, CST 196

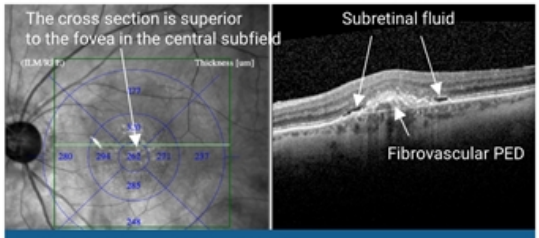


Month 6:
BCVA 46 CST 194

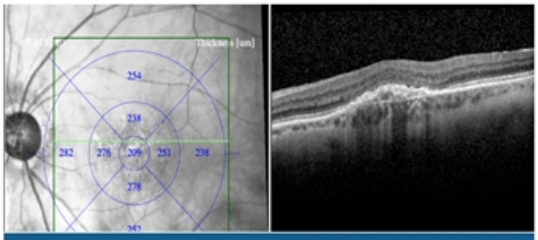
Source: Clearside data on file. | Previous treatments prior to screening.

6 Month Case Study: Durable Stability After CLS-AX

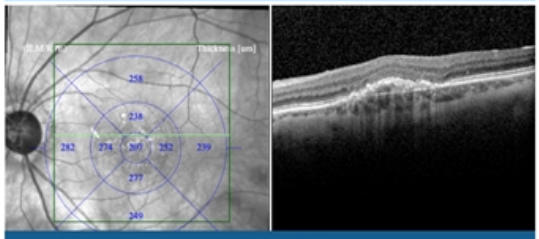
Cohort 3, Subject 6: 49 prior anti-VEGF injections with persistent subretinal fluid in superior central subfield
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



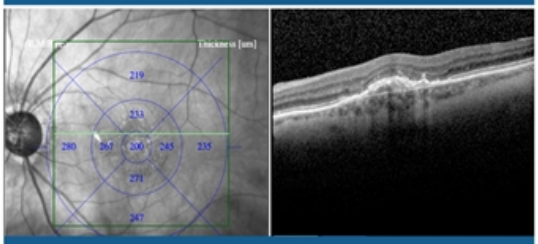
Screening: Aflibercept
BCVA 72, CST 262



Baseline: CLS-AX
BCVA 71, CST 209



Month 3
BCVA 71, CST 207



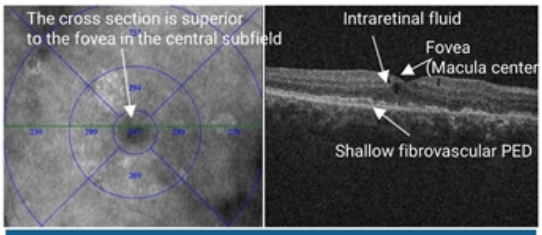
Month 6
BCVA 69, CST 200

CLEARSIDE BIOMEDICAL

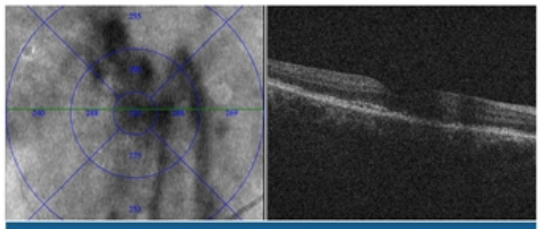
Source: Clearside data on file. | Previous treatments prior to screening.

6 Month Case Study: Durable Stability After CLS-AX

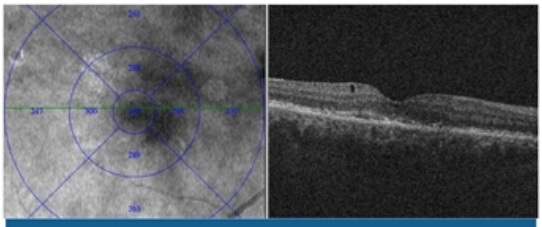
Cohort 4, Subject 5: 29 prior anti-VEGF injections with persistent PED and intraretinal fluid in superior central subfield
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



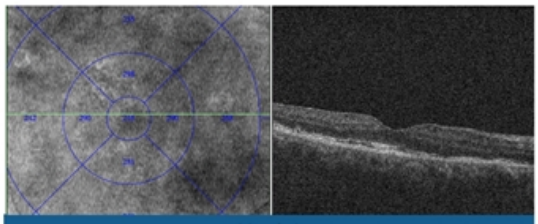
Screening: Aflibercept
BCVA 70, CST 244



Baseline: CLS-AX
BCVA 70, CST 234



Month 3
BCVA 69, CST 249

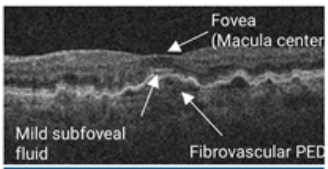


Month 6
BCVA 73, CST 246

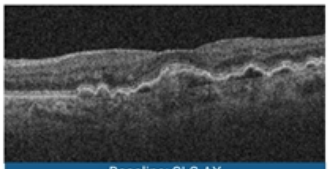
Source: Clearside data on file. | Previous treatments prior to screening.

6 Month Case Study: Durable Stability After CLS-AX

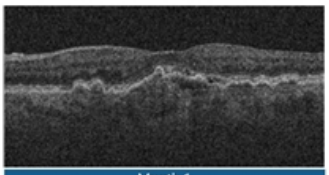
Cohort 4, Subject 6: 29 prior anti-VEGF injections with PED and mild subfoveal at screen
Stable anatomy, BCVA and CST for 6 months after CLS-AX with no additional therapy



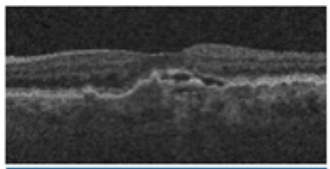
Screening: Aflibercept
BCVA 75, CST 184



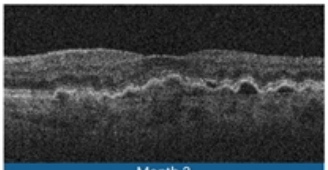
Baseline: CLS-AX
BCVA 74, CST 197



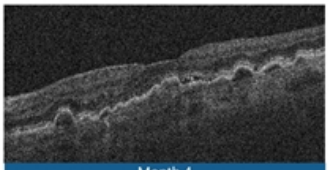
Month 1
BCVA 79, CST 198



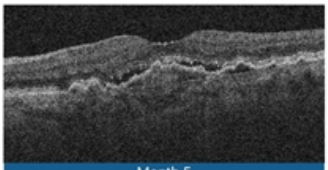
Month 2
BCVA 79, CST 227



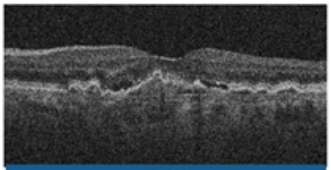
Month 3
BCVA 79, CST 201



Month 4
BCVA 80, CST 215



Month 5
BCVA 77, CST 234



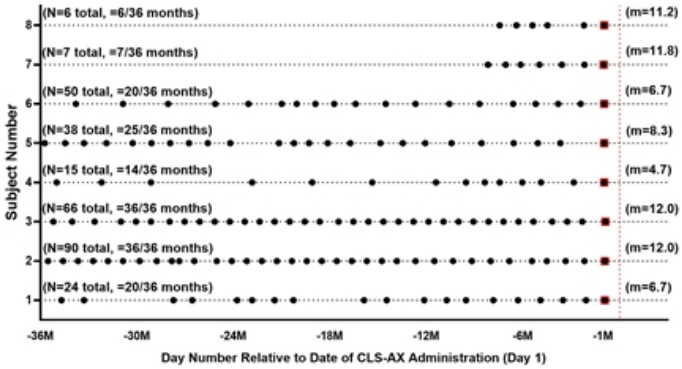
Month 6
BCVA 75, CST 211

Source: Clearside data on file. | Previous treatments prior to screening.


OASIS
Individual Patient
Data

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

COHORT 3: 0.5 mg

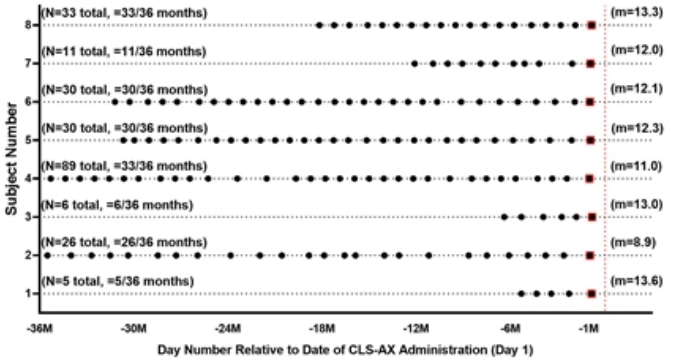


● Prior nAMD Treatment ■ IVT Aflibercept (Screening, Visit 1)

(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)).

Source: Clearside data on file.

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

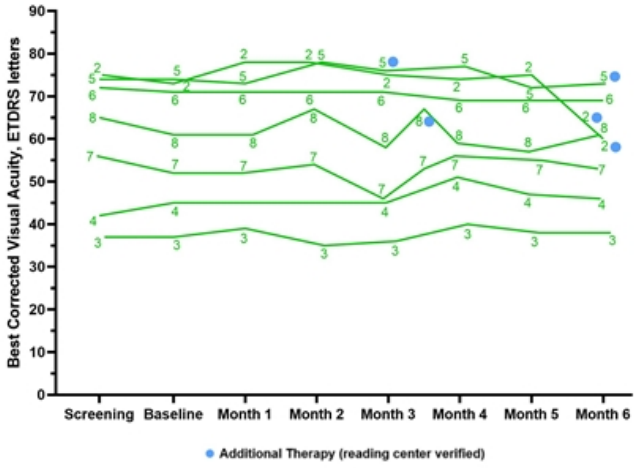
** Two interventions within window*

Red = not treated per protocol defined criteria

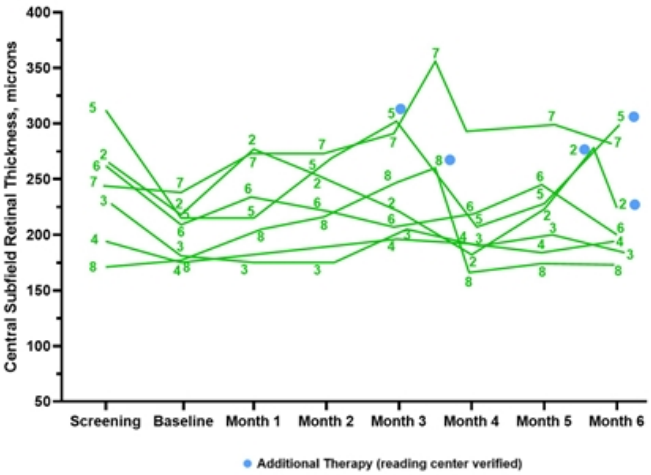
Assessment for additional treatment with aflibercept:
Decrease from best measurement of ≥10 letters in BCVA with exudation; Increase in CST >75 microns; A vision-threatening hemorrhage

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

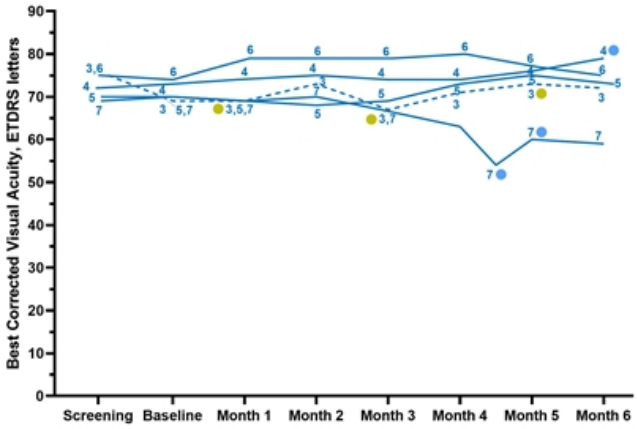


CLEARSIDE BIOMEDICAL

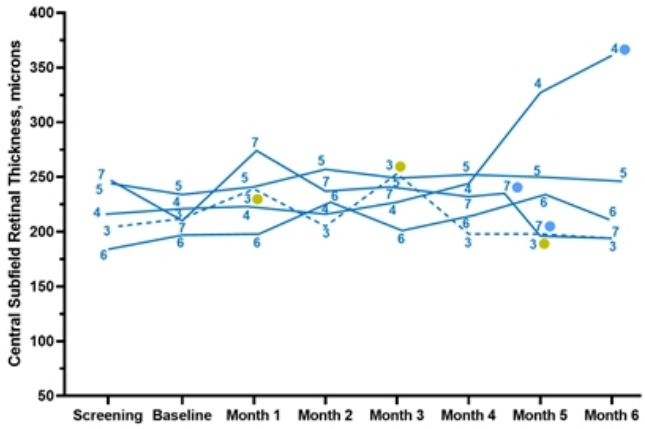
Source: Clearside data on file.
Note: Demonstrates data from scheduled and unscheduled visits.

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)

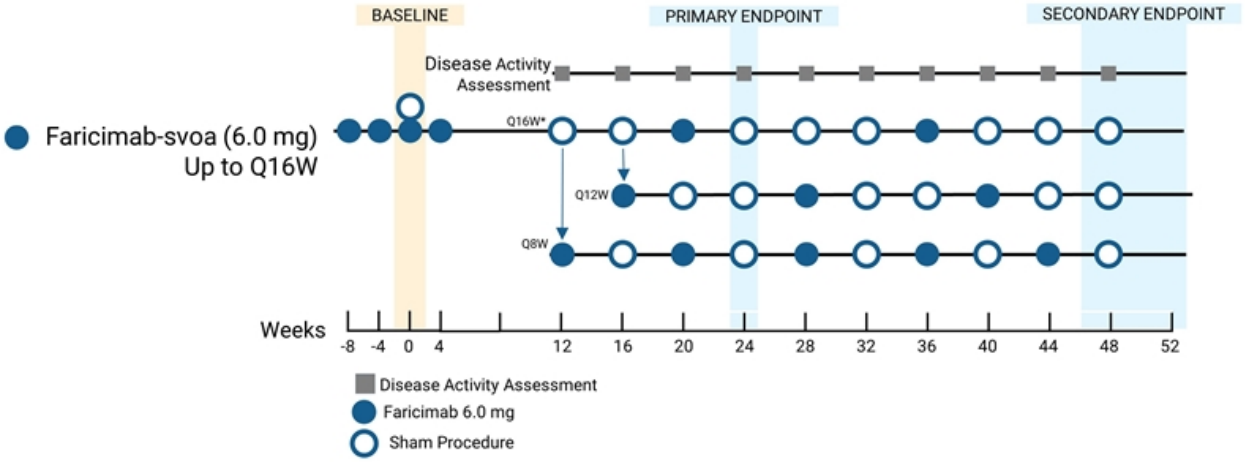
Dotted line = patient received additional therapy not per protocol (not reading center verified or physician discretion)

CLEARSIDE BIOMEDICAL

Source: Clearside data on file.
Note: Demonstrates data from scheduled and unscheduled visits.


OASIS
Appendix

ODYSSEY Phase 2b Trial: Control Arm Dosing Per Label



*Dosing frequency to be used if no active disease assessed during study


CLEARSIDE
BIOMEDICAL
NASDAQ: CLSD

Clearside Biomedical Announces Positive 6-Month Results from OASIS Extension Study with Suprachoroidal CLS-AX (axitinib injectable suspension) in Wet AMD

- Suprachoroidal CLS-AX Resulted in Favorable Safety Data, Durability and Biologic Effect Over 6 Months in Treatment-Experienced Anti-VEGF Sub-Responders -

- 67% of Extension Study Participants Went at Least 6 Months Without Needing Additional Treatment -

- Extension Participants Experienced a 77 - 85% Reduction in Treatment Burden Over 6 Months -

- Webcast and Conference Call Today at 8:30 A.M. ET Hosted by Management and Including Key Opinion Leader, Mark R. Barakat, M.D. -

ALPHARETTA, Ga., February 2, 2023 - Clearside Biomedical, Inc. (Nasdaq: CLSD), a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®), announced today positive results from the Extension Study of its OASIS Phase 1/2a clinical trial of CLS-AX (axitinib injectable suspension) administered by suprachoroidal injection via Clearside's SCS Microinjector® in neovascular age-related macular degeneration (wet AMD) participants. These results include the final six-month data from all participants in the Extension Study and augment the previously reported 3-month results and interim extension data.

Thomas A. Ciulla, M.D., M.B.A., Chief Medical Officer and Chief Development Officer, said, "The positive data from our OASIS Extension Study reinforces our belief that CLS-AX has the potential to reduce treatment burden in patients with wet AMD while maintaining stable visual acuity. In all participants in the trial, CLS-AX was well tolerated and demonstrated an excellent safety profile across all timepoints and doses. Importantly, the full extension data reported today showed promising durability with 67% of participants going at least six months without additional treatment, and 50% of participants going beyond six months. With these favorable data, we are actively preparing for and expect to initiate a randomized, controlled, double-masked, Phase 2b clinical trial, called ODYSSEY, in the first quarter of this year, with the primary endpoint readout anticipated in mid-2024."

George Lasezkay, Pharm.D., J.D., Clearside's President and Chief Executive Officer, commented, "We made tremendous progress in 2022 with the commercialization of our first suprachoroidal product by Bausch + Lomb and the positive safety and durability results from our Phase 1/2a OASIS trial. As we advance our CLS-AX wet AMD program with the initiation of our ODYSSEY Phase 2b trial, we continue to build on this significant momentum and will further increase awareness of the broad potential in delivering therapies to the back of the eye using our proprietary SCS® platform technology."

"This CLS-AX data demonstrating stable visual acuity with durability up to and beyond six months is very encouraging as we look to lower the treatment burden for wet AMD patients. As the management of wet AMD expands to include therapeutic options with different mechanisms of action, such as axitinib and faricimab, it makes sense to compare outcomes to these therapies in future clinical trials. CLS-AX, with suprachoroidal delivery and an alternate mechanism of action from standard of care anti-VEGF products, may prove to be a differentiated therapy for wet AMD and other retinal diseases," added Mark R. Barakat, M.D., Director of Retinal Research Institute, Retinal Consultants of Arizona, and Clinical Assistant Professor of Ophthalmology, University of Arizona College of Medicine—Phoenix.

Conference Call & Webcast Details

Clearside will host a webcast and conference call with accompanying slides today at 8:30 a.m. ET, including comments by management and retinal expert, Dr. Mark R. Barakat. The live and archived webcast may be accessed on the Clearside website under the Investors section: Events and Presentations. The live call can be accessed by dialing (888) 506-0062 (domestic) or (973) 528-0011 (international) and entering conference code: 676850.

OASIS Data Summary

(Extension Study data slides are provided on the Clearside website under the Investors section: Events and Presentations.)

The OASIS Phase 1/2a trial is complete for both the 3-month dose-escalation portion and the 3-month Extension Study. The study included four cohorts at the following doses: Cohort 1 at 0.03 mg; Cohort 2 at 0.1 mg; Cohort 3 at 0.5 mg; Cohort 4 at 1.0 mg. Participants from Cohorts 2, 3 and 4 who rolled over into the Extension Study were followed for a total of 6 months after a single dose of CLS-AX. Participants enrolled in OASIS were heavily anti-VEGF treatment experienced with active disease[1] at screening, which was confirmed by an independent reading center.

Safety and Tolerability Results in All Cohorts in the 3-Month Study (n=27) & 6-Month Extension Study (n=14)

- No serious adverse events (SAEs), no treatment emergent adverse events (TEAEs) related to study treatment, and 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 detachments, endophthalmitis, or adverse events related to intraocular pressure.

Durability in the 6-Month Extension Study in Cohorts 3 & 4 at higher doses (n=12)

- 77% - 85% reduction in treatment burden was observed compared to the average monthly injections in the six months before CLS-AX administration.
- Participants 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 in the 6-Month Extension Study in Cohorts 3 & 4 (n=12)

- CLS-AX showed signs of biologic effect with stable mean best corrected visual acuity (BCVA) and stable mean central subfield thickness (CST) to the 6-month timepoint.
- On Optical Coherence Tomography (OCT) images, anatomical signs of TKI biologic effect were observed in anti-VEGF treatment experienced sub-responders.

About the Planned ODYSSEY Phase 2b Clinical Trial

ODYSSEY will be a multi-center, randomized, double-masked Phase 2b clinical trial to assess a total of approximately 110 treatment-naïve participants with wet AMD. In addition to loading doses of faricimab, participants will be randomized 1:1 to receive either CLS-AX administered by suprachoroidal injection via Clearside's SCS Microinjector®, or intravitreal faricimab dosed per approved prescribing information[2]. The objectives of the trial are to demonstrate comparable mean change in BCVA from baseline between treatment arms with improved durability and reduced treatment burden for the CLS-AX arm, measured at 6 and 12 months.

Trial Design

- Loading Doses: Participants in both arms will receive 4 monthly faricimab (6.0 mg) loading doses. In the CLS-AX arm, participants will also receive one dose of CLS-AX (1.0 mg) at the same visit as the third loading dose of faricimab (baseline).

- Monthly Disease Activity Assessments (DAA): DAAs begin 2 months after the last faricimab loading dose to determine need for retreatment. The retreatment criteria include decrease in BCVA, increase in CST, or new macular hemorrhage[3].
- Subsequent Treatments:
  - In the 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.
  - In the 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).
- Key inclusion criteria: Treatment naïve wet AMD participants with subfoveal choroidal neovascularization (CNV) secondary to wet AMD, and BCVA of 78–24 letters.
- Endpoints: Primary endpoint is the mean change from baseline in BCVA at 6 months (Week 24 Visit) from baseline. Key secondary endpoints include mean change in CST and treatment burden reduction as measured by total injections. All endpoints will be measured at 6 months (Week 24 Visit) and 12 months (Week 48 & 52 Visits combined) from baseline.

As of December 31, 2022, Clearside's cash and cash equivalents totaled $48.3 million. This amount is an unaudited and preliminary estimate that (i) represents the most current information available to management as of the date hereof, (ii) is subject to completion of financial closing and auditing procedures that could result in significant changes to the estimated amount, and (iii) does not present all information necessary for an understanding of Clearside's financial condition as of, and results of operations for the year ended, December 31, 2022. Accordingly, you should not place undue reliance on this preliminary estimate.

About the OASIS Phase 1/2a Clinical Trial

OASIS was an open-label, dose-escalation Phase 1/2a trial in wet AMD participants to assess the safety and tolerability of a single dose of CLS-AX administered by suprachoroidal injection via Clearside's SCS Microinjector®. Eligible participants were those who demonstrated stable visual acuity following two or more previous injections with an intravitreal anti-VEGF agent. All enrolled participants underwent diagnostic imaging on screening, followed by masked reading center confirmation of persistent active disease.

The study included four cohorts totaling 27 patients at the following doses: Cohort 1 at 0.03 mg; Cohort 2 at 0.1 mg; Cohort 3 at 0.5 mg; Cohort 4 at 1.0 mg. Enrolled patients received aflibercept at the first visit followed by a single dose of CLS-AX at the second visit one month later. The primary endpoint for the trial was assessment of the safety and tolerability of CLS-AX for the 3 months following the administration of CLS-AX, and secondary endpoints evaluated the pharmacokinetics, visual function, ocular anatomy, and the need for additional treatment with intravitreal aflibercept.

A 3-month Extension Study was conducted to follow patients in Cohorts 2, 3 and 4 who chose to continue for a total of six months. Additional information on the Phase 1/2a trial can be found on clinicaltrials.gov NCT04626128 and the extension study can be found at NCT05131646.

About CLS-AX (axitinib injectable suspension)

CLS-AX (axitinib injectable suspension) is a proprietary suspension of axitinib for suprachoroidal injection. Axitinib is a tyrosine kinase inhibitor (TKI) currently approved to treat renal cell cancer that achieves pan-VEGF blockade, directly inhibiting VEGF receptors-1, -2, and -3 with high potency and specificity. Clearside believes this broad VEGF blockade may have efficacy advantages over existing retinal therapies by acting at a different level of the angiogenesis cascade and may benefit patients who sub-optimally respond to current, more narrowly focused anti-VEGF therapies. Suprachoroidal injection of this proprietary suspension of axitinib has demonstrated meaningful potential in preclinical studies in multiple species and in a Phase 1/2a clinical trial. With suprachoroidal administration of axitinib, there is the potential to achieve prolonged duration and targeted delivery to affected tissue layers. Clearside is developing CLS-AX as a long-acting therapy for the treatment of retinal diseases.

About Neovascular Age-Related Macular Degeneration (wet AMD)

Age-related macular degeneration causes a progressive loss of central vision and is the most common cause of legal blindness in individuals over age 55. Wet AMD is generally caused by abnormal blood vessels that leak fluid or blood into the macula, the part of the retina responsible for central vision, and accounts for the majority of vision loss in patients with this disorder. In the U.S., approximately 11 million patients are living with AMD, and about 20% have the wet form. Current treatments require life-long, frequent injections to maintain efficacy. This treatment regimen tends to cause a treatment burden for patients resulting in reduced compliance and under-treatment leading to potentially limited outcomes.

About Clearside's Suprachoroidal Space (SCS®) Injection Platform and SCS Microinjector®

Clearside's patented, proprietary suprachoroidal space (SCS®) injection treatment approach offers unprecedented access to the back of the eye where sight-threatening disease often occurs. The Company's unique platform is inherently flexible and intended to work with established and new formulations of medications. Clearside's proprietary SCS Microinjector® can be used to inject a wide variety of drug candidates that are specifically formulated to be delivered via suprachoroidal injection. The SCS Microinjector provides targeted delivery to potentially improve efficacy and compartmentalization of medication to reduce or eliminate toxic effects on non-diseased cells. The SCS Microinjector is composed of a syringe and two 30-gauge hollow microneedles of varying lengths, each less than 1.2 millimeters, within a custom-designed hub that optimizes insertion and suprachoroidal administration of drugs.

About Clearside Biomedical, Inc.

Clearside Biomedical, Inc. is a biopharmaceutical company revolutionizing the delivery of therapies to the back of the eye through the suprachoroidal space (SCS®). Clearside's SCS injection platform, utilizing the Company's proprietary SCS Microinjector®, enables an in-office, repeatable, non-surgical procedure for the targeted and compartmentalized delivery of a wide variety of therapies to the macula, retina or choroid to potentially preserve and improve vision in patients with sight-threatening eye diseases. Clearside is developing its own pipeline of small molecule product candidates for administration via its SCS Microinjector and strategically partners its SCS injection platform with companies utilizing other ophthalmic therapeutic innovations. Clearside's first product, XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use, is commercially available in the U.S. For more information, please visit www.clearsidebio.com.

1 Active persistent disease defined as active subfoveal choroidal neovascularization (CNV) secondary to AMD in the study eye confirmed by an independent reading center as leakage from a subfoveal CNV on fluorescein angiography and intra-retinal or sub-retinal fluid on OCT central subfield).
2 Refer to Prescribing Information for VABYSMO® (faricimab-svoa) injection, for intravitreal use. VABYSMO is a registered trademark of Genentech.
3 Retreatment criteria include:

- 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.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan”, “potential”, “will”, and similar expressions, and are based on Clearside’s current beliefs and expectations. These forward-looking statements include statements regarding the clinical development of CLS-AX, timeline for initiating the ODYSSEY Phase 2b clinical trial for CLS-AX, the expected timing of data from the ODYSSEY clinical trial, Clearside’s cash and cash equivalents as of December 31, 2022 and the potential benefits of CLS-AX and other product candidates using Clearside’s SCS Microinjector®. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Clearside’s reliance on third parties over which it may not always have full control, uncertainties regarding the COVID-19 pandemic and other risks and uncertainties that are described in Clearside’s Annual Report on Form 10-K for the year ended December 31, 2021, filed with the U.S. Securities and Exchange Commission (SEC) on March 11, 2022, Clearside’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 filed with the SEC on November 9, 2022 and Clearside’s other Periodic Reports filed with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Clearside as of the date of this release, and Clearside assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

###

Investor and Media Contacts:

Jenny Kobin
Remy Bernarda
ir@clearsidebio.com
(678) 430-8206

Source: Clearside Biomedical, Inc.