UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): August 12, 2022

UNITY BIOTECHNOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38470**	**26-4726035**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

285 East Grand Ave.
South San Francisco, CA 94080
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 416-1192

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 $0.0001 per share	**UBX**	**The Nasdaq Global Select Market**

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 8.01 Other Events.

On August 12, 2022, Unity Biotechnology, Inc. ("UNITY" or the "Company") announced positive data from its Phase 2 BEHOLD study of UBX1325 in patients with diabetic macular edema (DME). The Company will host a conference call today, Friday, August 12, 2022, at 8:00 a.m., Eastern Time, to discuss the data results.

A copy of the press release and the presentation that will be referenced during the conference call are filed as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release titled "UNITY Biotechnology Announces Positive Data in Phase 2 BEHOLD Study of UBX1325 in Patients with Diabetic Macular Edema," dated August 12, 2022
99.2	Presentation of Unity Biotechnology, Inc. dated August 12, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

UNITY BIOTECHNOLOGY, INC.

Date: August 12, 2022

By: /s/ Anirvan Ghosh
Anirvan Ghosh, Ph.D.
Chief Executive Officer

Exhibit 99.1

UNITY Biotechnology Announces Positive Data in Phase 2 BEHOLD Study of UBX1325 in Patients with Diabetic Macular Edema

A single injection of UBX1325 led to a progressive, statistically significant, and clinically meaningful improvement in mean Best Corrected Visual Acuity (BCVA) at 12- and 18-weeks compared to sham treatment

UBX1325 treatment also stabilized retinal structure, as measured by central subfield thickness (CST) at 12- and 18-weeks, as compared to worsening in sham-treated patients

The treatment effect was seen in a patient population with visual acuity deficits and residual retinal fluid despite frequent and recent anti-VEGF therapy

UNITY to host investor call with retinal expert Robert Bhisitkul, M.D., Ph.D., today, August 12, at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., August 12, 2022 – UNITY Biotechnology, Inc. ("UNITY") [Nasdaq: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced 12- and 18-week data from its Phase 2 BEHOLD study of UBX1325, a senolytic Bcl-xL inhibitor, in patients with diabetic macular edema (DME).

At 18 weeks after a single UBX1325 injection, the mean change in BCVA of UBX1325-treated subjects was an increase of 6.1 ETDRS letters, representing an improvement of +5.0 ETDRS letters compared to sham-treated subjects ($p = 0.0368$). In addition, patients treated with UBX1325 maintained CST compared to sham-treated patients who demonstrated progressive worsening of CST (i.e., increased retinal thickness) through 18 weeks. The separation of UBX1325-treated patients from sham-treated patients at 18 weeks in measures of both visual function and retinal structure following a single UBX1325 injection suggests that one dose could have a durable therapeutic effect. The current standard of care for DME with the leading anti-VEGF therapeutic requires 3-5 monthly loading doses followed by every 8-week dosing, imposing a significant treatment burden on patients.

"The 12- and 18-week BEHOLD results are especially impressive considering that UBX1325 was given as a single injection in a patient population in which anti-VEGF treatment was no longer providing optimal benefit," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "The vision gains observed are greater than what has been previously reported with the standard of care in similar patient populations, and the durability of effect suggests that UBX1325 could address the large unmet need for longer-lasting, disease-modifying treatments for patients with DME. These data represent an important and exciting step in validating the senolytic therapeutic concept that is core to UNITY's platform."

Evidence of favorable safety, visual acuity improvement, and structural stability in a difficult-to-treat patient population:

Overall Safety

UBX1325 demonstrated a favorable safety and tolerability profile with no cases of intraocular inflammation, retinal vein occlusion, endophthalmitis, or vasculitis.

At 12 weeks (primary analysis set of 65 patients)

- Patients enrolled in BEHOLD were receiving regular anti-VEGF treatment prior to enrollment into the study (mean rate of approximately 4 injections in the preceding 6 months) with the last anti-VEGF injection occurring 3 – 6 weeks prior to randomization
- Patients treated with a single injection of UBX1325 had a mean improvement in BCVA of +4.7 ETDRS letters from baseline compared to +1.3 ETDRS letters in sham-treated patients (p=0.1148)
- Patients treated with UBX1325 had a mean change in CST of -1.4 microns from baseline compared to +40.3 microns in sham-treated patients (p=0.0747)

At 18 weeks (primary analysis set of 54 patients)

- Patients treated with UBX1325 had a mean improvement in BCVA of +6.1 ETDRS letters from baseline compared to +1.1 EDTRS letters in sham-treated patients (p=0.0368)
- Patients treated with UBX1325 had a mean change in CST of +3.2 microns from baseline compared to +53.5 microns in sham-treated patients (p=0.0719)

Based on pre-defined proof-of-concept criteria of alpha=0.15, the study demonstrated a statistically significant treatment effect for both BCVA and CST at both 12- and 18-weeks.

“A 6.1-letter gain from baseline in DME patients who had been actively receiving anti-VEGF treatment and had vision loss with persistent fluid is a clinically meaningful and impressive outcome,” said Arshad M. Khanani, M.D., M.A., FASRS, Director of Clinical Research at Sierra Eye Associates, Reno, Nevada. “The results are particularly noteworthy considering that there is a progressive improvement in vision through 18 weeks after a single injection of UBX1325. A treatment based on a new mechanism of action that shows a meaningful and sustained improvement in BCVA and stability of CST while also reducing the frequency of injections would be of huge value for patients with DME.”

The proof-of-concept Phase 2 BEHOLD study is a multi-center, randomized, double-masked, sham-controlled study designed to evaluate the safety, tolerability, efficacy and durability of a single 10 mcg dose of UBX1325 in patients with DME evaluated though 24 weeks. The study enrolled 65 patients being actively treated with anti-VEGF who had a visual acuity deficit (73 ETDRS letters, approximately 20/40, or worse) and residual retinal fluid (CST $\geq$300 microns). Patients have the option of rolling over to a 48-week long term extension and a majority of patients who have completed their 24-week visit have opted to remain in the study. More information about the study is available here (NCT04857996).

“Bolstered by positive proof-of-concept data, we believe UBX1325 could represent a much-needed alternative to all other currently available treatments for DME, including the standard of care anti-VEGF therapy,” said Jamie Dananberg, M.D., chief medical officer of UNITY. “The 12- and 18-week results indicate that a single injection of UBX1325 resulted in significantly greater letter gains and stabilization of retinal structure than the sham treatment, but also likely altered the disease trajectory of these patients who had been on anti-VEGF treatment. We are greatly encouraged by these findings and look forward to our upcoming 24-week BEHOLD (DME) and 16-week ENVISION (wet AMD) study readouts in the months ahead.”

Conference Call at 8:00 a.m. ET Today

UNITY will host a video conference call and webcast for investors and analysts today at 8:00 a.m. ET to discuss the most recent UBX1325 clinical data. Dr. Robert Bhisitkul, M.D., Ph.D., professor of ophthalmology and director of the Retina Fellowship at University of California, San Francisco, as well as members of the UNITY senior management team, will lead the discussion on the 12- and 18-week BEHOLD study results. The live webcast can be accessed in the “Investors and Media” section of our website, www.unitybiotechnology.com, under “Events & Presentations” or by clicking here. A replay will be available two hours after the completion of the call and can be accessed in the “Investors & Media” section of our website, under “Events and Presentations.”

About UBX1325

UBX1325 is an investigational compound being studied for age-related diseases of the eye, including diabetic macular edema (DME), age-related macular degeneration (AMD), and diabetic retinopathy (DR) that is not approved for any use in any country. UBX1325 is a potent small molecule inhibitor of Bcl-xL, a member of the Bcl-2 family of apoptosis regulating proteins. UBX1325 is designed to inhibit the function of proteins that senescent cells rely on for survival. In a Phase 1 clinical study in advanced wet AMD and DME, UBX1325 showed a favorable safety profile and improvements in visual acuity sustained through 24 weeks following a single intravitreal injection. In preclinical studies, UNITY has demonstrated that targeting Bcl-xL with UBX1325 preferentially eliminated senescent cells from diseased tissue while sparing cells in healthy tissue. UNITY's goal with UBX1325 is to transformationally improve real-world outcomes for patients with DME, AMD, and DR.

About UNITY

UNITY is developing a new class of therapeutics to slow, halt, or reverse diseases of aging. UNITY's current focus is on creating medicines to selectively eliminate or modulate senescent cells and thereby provide transformative benefit in age-related ophthalmologic and neurologic diseases. More information is available at www.unitybiotechnology.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements including statements related to UNITY's understanding of cellular senescence and the role it plays in diseases of aging, the potential for UNITY to develop therapeutics to slow, halt, or reverse diseases of aging, including for ophthalmologic and neurologic diseases, our expectations regarding potential benefits, activity, effectiveness, and safety of UBX1325, the potential for UNITY to successfully commence and complete clinical studies of UBX1325 for DME, AMD, and other ophthalmologic diseases, the expected timing and nature of results of our studies of UBX1325 including BEHOLD and ENVISION, including the risk that interim results of our clinical studies may not be indicative of future results, the timing of the expected commencement, progression, and conclusion of our studies including those of UBX1325, and UNITY's expectations regarding the sufficiency of its cash runway. These statements involve substantial known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements, including the risk that the COVID-19 worldwide pandemic may continue to negatively impact the development of preclinical and clinical drug candidates, including delaying or disrupting the enrollment of patients in clinical trials, risks relating to the uncertainties inherent in the drug development process, and risks relating to UNITY's understanding of senescence biology. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this press release represent our views as of the date of this release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this release. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of UNITY in general, see UNITY's most recently filed Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the Securities and Exchange Commission on August 12, 2022, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission.

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Exhibit 99.2

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UBX1325
Phase 2 BEHOLD DME Study
12- and 18-Week Data

Robert Bhisitkul, M.D., Ph.D.
Professor of Ophthalmology, UCSF

Anirvan Ghosh, CEO
Jamie Dananberg, CMO
Lynne Sullivan, CFO

August 12, 2022

Special Note Regarding Forward-Looking Statements

This presentation and the accompanying oral commentary contain forward-looking statements including statements related to Unity Biotechnology Inc.'s ("UNITY's") understanding of cellular senescence and the role it plays in diseases of aging, the potential for UNITY to develop therapeutics to slow, halt, or reverse diseases of aging, including for ophthalmologic and neurologic diseases, the potential for UNITY to successfully commence and complete clinical studies of UBX1325 for DME, AMD, and other ophthalmologic diseases, the expected timing of enrollment and results of the clinical trials in UBX1325, and UNITY's expectations regarding the sufficiency of its cash runway. These statements involve substantial known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements, including the risk that the COVID-19 worldwide pandemic may continue to negatively impact the development of preclinical and clinical drug candidates, including delaying or disrupting the enrollment of patients in clinical trials, risks relating to the uncertainties inherent in the drug development process, including the risk that interim results of our clinical studies may not be indicative of future results, and risks relating to UNITY's understanding of senescence biology. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this press release represent our views as of the date of this release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this release. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of UNITY in general, see UNITY's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the Securities and Exchange Commission on August 12, 2022, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission. This presentation concerns drug candidates that are under clinical investigation which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated. This presentation does not constitute an offer or invitation for the sale or purchase of securities and has been prepared solely for informational purposes.

UBX1325 Achieved Proof-of-Concept in Patients with Diabetic Macular Edema (DME)

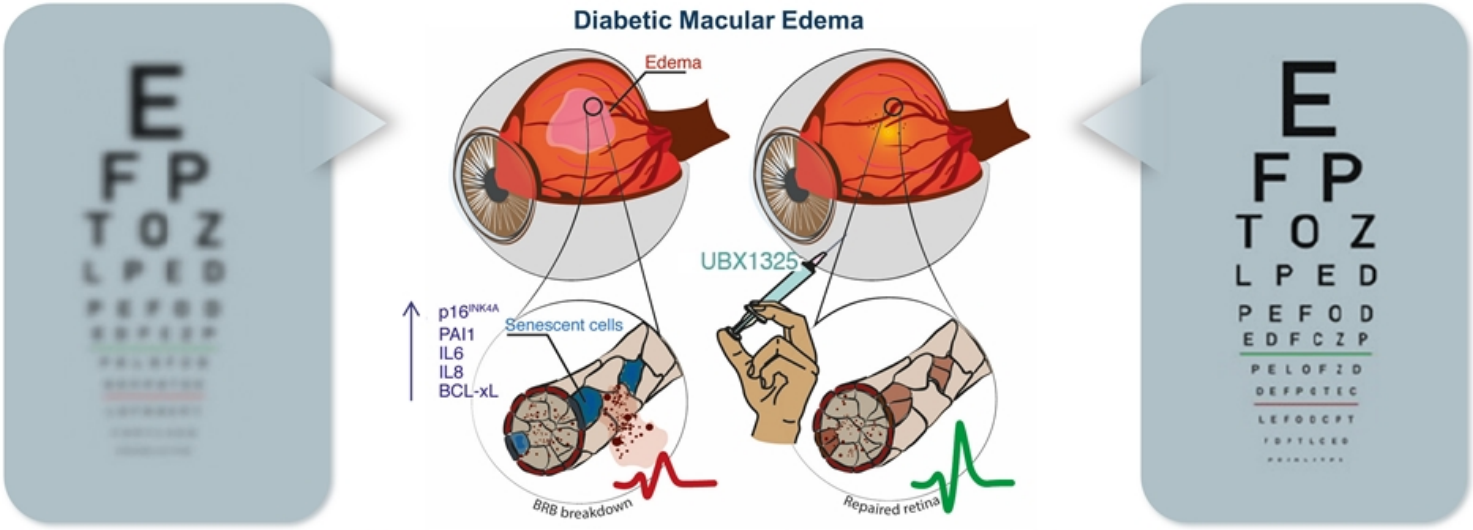
Phase 2 Data Highlights

- UBX1325, the first senolytic drug being explored in eye disease, had a favorable safety and tolerability profile, with no evidence of intra-ocular inflammation
- A single dose of UBX1325 led to a progressive, statistically significant improvement in vision as measured by BCVA out to 18 weeks in DME patients
- Retinal structure, as measured by CST, was maintained through 18 weeks in UBX1325-treated patients, compared to worsening of CST in sham-treated patients
- This novel mechanism of action could benefit patients as monotherapy or in combination with anti-VEGF agents

Built on UNITY's Senescent Cell Biology Platform

- Preclinical mechanism of action and efficacy data support senolytic therapeutic hypothesis
- Mechanism has broad implication for diseases of aging

UNITY Is Developing Senolytic Medicines to Eliminate Senescent Cells to Restore Vascular Health and Improve Vision

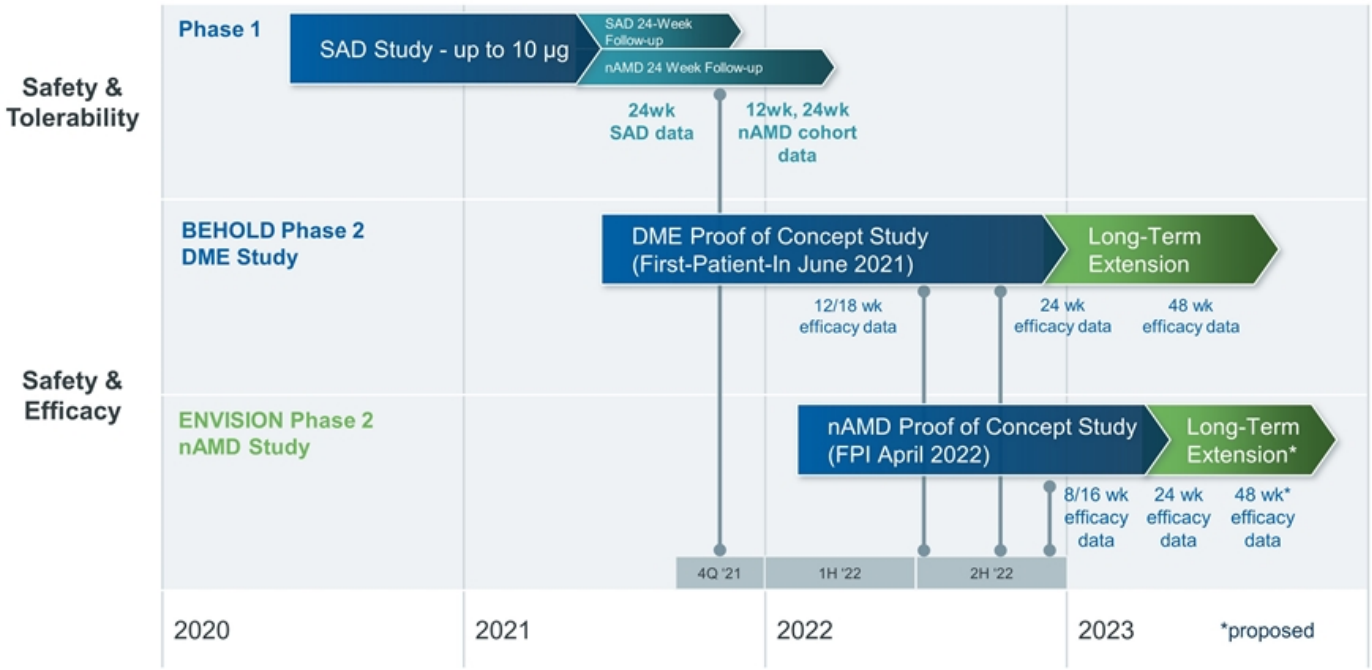


DME:
- Increased senescence burden
- Retinal vasculature affected
- Blood retinal barrier (BRB) Breakdown
- Loss of vision

DME treated with Senolytic intended results:
- Senescent cells removed
- Retinal vasculature restored
- Improvement in vision

UNITY illustration.

UBX1325 Clinical Program Overview



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UBX1325 Phase 2 BEHOLD Study

Historic Data on DME Patients treated with Standard of Care

Differences in Patient Population in Ph1 and Ph2 Studies

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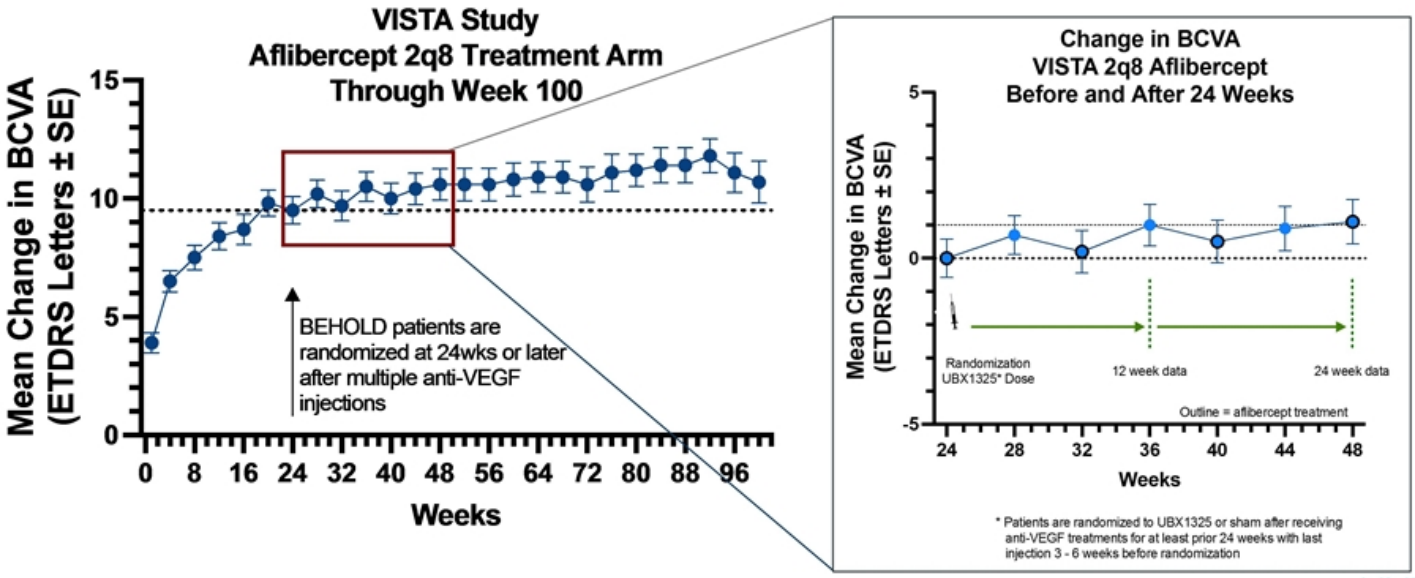
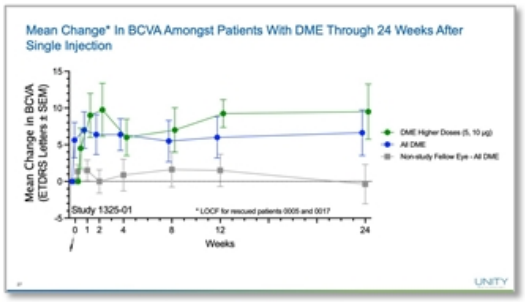
Context for 12w DME Data: After Anti-VEGF Effect Has Plateaued, Patients Gain Approximately 1 Letter in Subsequent 6 Months on Aflibercept Treatment



Comparing Patient Populations Between UBX1325 Phase 1 Study and Phase 2 BEHOLD Study

Phase 1 Design

- Patients with advanced DME and nAMD
- No previous anti-VEGF treatment for ≥3 months and for whom anti-VEGF agents were no longer considered beneficial



Phase 2 (BEHOLD) Design

- Patients with DME with residual visual acuity deficits and macular fluid
- On active anti-VEGF treatment regimen for ≥6 months until randomization

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UBX1325 Phase 2 BEHOLD Study

12- and 18-Week Data in Patients With DME

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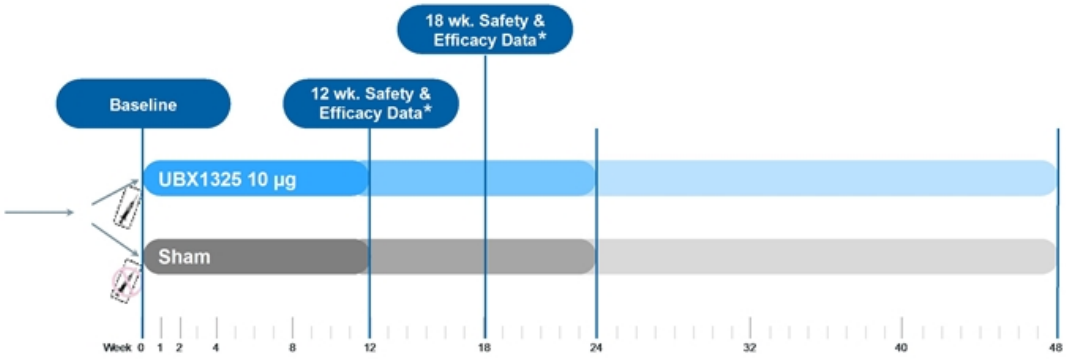
BEHOLD Study Design, Patient Population, and Endpoints

Patient Population

Individuals with **Diabetic Macular Edema** (with moderate diabetic proliferative retinopathy or better), **residual retinal fluid** (≥300 µm) and **visual acuity deficit** (73 ETDRS letters or worse) despite having received **repeated anti-VEGF** treatments (≥2 injections over last 6 months, last 3-6 weeks prior to randomization). The majority of subjects had 3 or more injections in preceding 6-month period.



* 65 patients were enrolled and used in the 12-Week analysis data set; 54 patients completed 18-Week visit for the respective analysis data set as of cutoff date

= UBX1325 injection

= Sham injection

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BEHOLD Study Endpoints and Methodology

- BEHOLD Endpoints:
  - Safety and Tolerability
  - Visual Acuity by Best Corrected Visual Acuity (BCVA, ETDRS Letters)
  - Macular Edema Central Subfield Thickness (CST, µm)
  - Proportion of patients receiving rescue

- Methodology
  - For all analyses, the primary data sets included 65 patients for data through 12-weeks and 54 patients through 18-weeks
  - BCVA and CST analyses were by Mixed Model Repeated Measures (MMRM), a widely used and accepted methodology for analyzing longitudinal data sets
  - This methodology effectively addresses post-rescue data so that the analyses presented reflect the treatment effect not confounded by anti-VEGF effect

12- and 18-Week BCVA Mean Changes From Baseline Based on MMRM Analysis

BCVA	Sham	UBX1325	Diff	P-Value
Week 12	1.3	4.7	3.4	0.1148*
Week 18	1.1	6.1	5.0	0.0368**

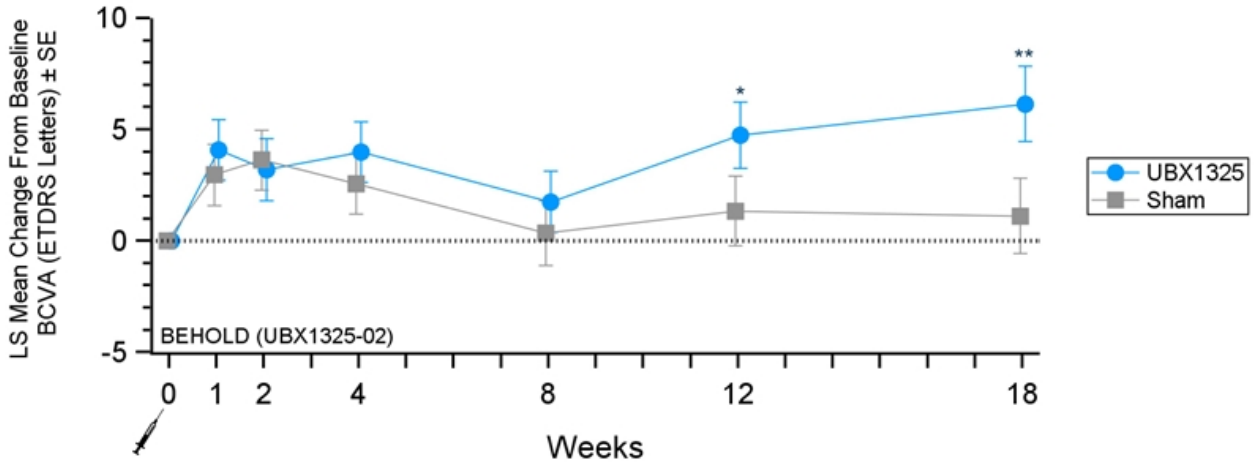

Table: VAL_t_14_2_1_23; Figure: VAL_ f_14_2_1_5

12- and 18-Week CST Mean Changes From Baseline Based on MMRM Analysis

CST	Sham	UBX1325	Diff	P-Value
Week 12	40.3	-1.4	-41.7	0.0747*
Week 18	53.5	3.2	-50.2	0.0719**

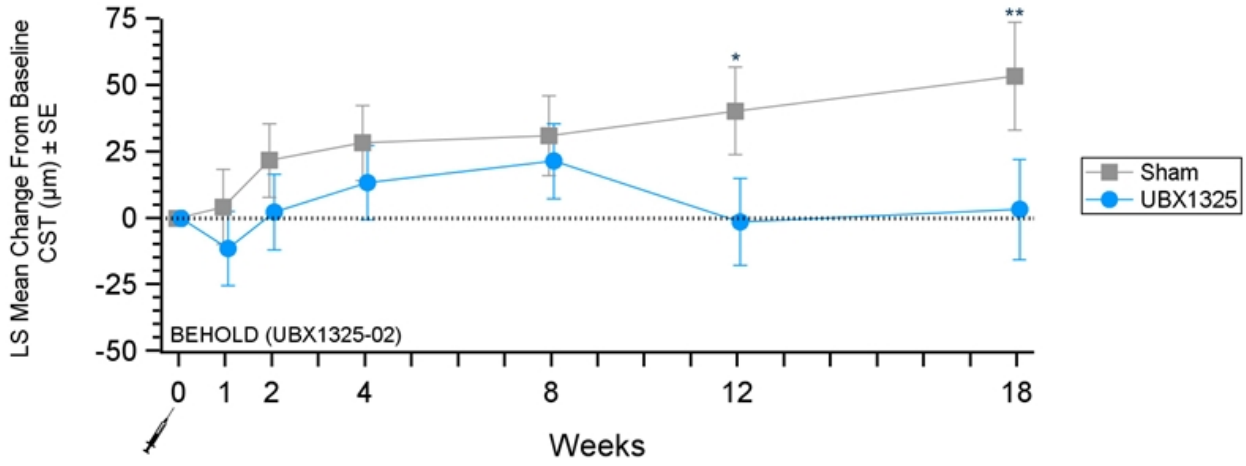

Table: VAL_t_14_2_1_24; Figure: VAL_14_2_1_6

Study Met Statistical Significance Based on Pre-specified Proof of Concept* Criteria for Both BCVA and CST

- PoC criteria were met for BCVA and CST at **Week 12** based on p-values

Week 12	Difference	p-value
BCVA (ETDRS letters)	3.4	**0.1148**
CST (µm)	-41.7	**0.0747**

- Treatment effect improved through **Week 18**

Week 18	Difference	p-value
BCVA (ETDRS letters)	5.0	**0.0368**
CST (µm)	-50.2	**0.0719**

- Numerically **greater use of rescue on Sham vs UBX1325** (12 vs 10 subjects with ≥1 rescue, 4 vs 3 patients with ≥2 rescues)
- Use of **rescue attenuated the treatment effect for BCVA**, as expected, but had a much smaller impact on CST

*This PoC study was powered for false positive rate (alpha) for BCVA of 15% or p<0.15

Table: VAL_t_14_2_1_23: VAL_t_14_2_1_24; VAL_t_14_2_2_1; VAL_t_14_2_1_2

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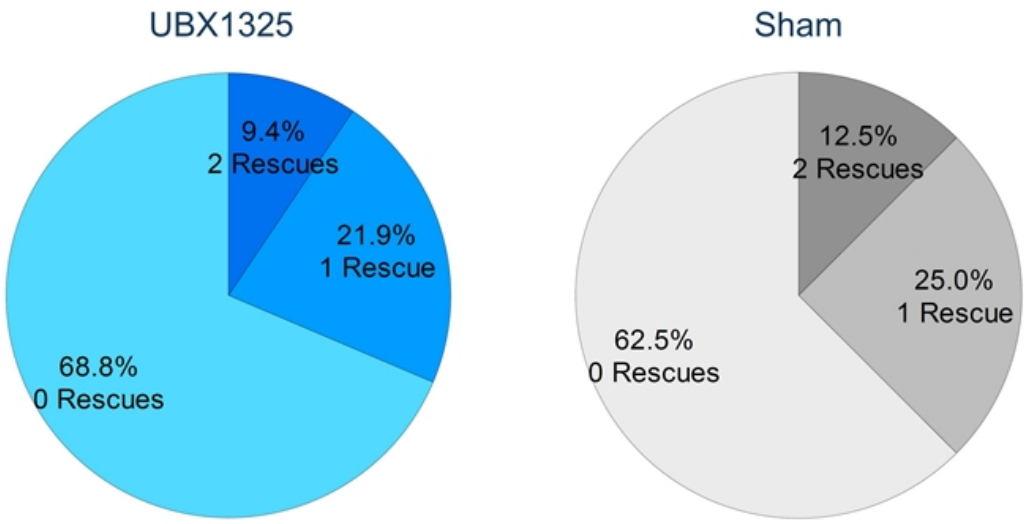
Summary of Subgroup Analyses

- In BEHOLD, 4 subgroup factors with 8 total subgroups (2 each) were evaluated based on baseline values for:
  - BCVA (≤60 vs. >60 ETDRS letters)
  - CST (≤400 vs. >400µm)
  - DRSS Score (<47 vs. ≥47)
  - A1c (≤7 vs. >7%)
- For the response of BCVA, there was a numeric advantage in all 8 subgroups for UBX1325-treated subjects
- For the response of CST, there was a numeric advantage in 7/8 subgroups for UBX1325-treated patients

Table: VAL_t_14_2_3_1,VAL_t_14_2_3_2,VAL_t_14_2_3_3,VAL_t_14_2_3_4,VAL_t_14_2_3_5,VAL_t_14_2_3_6,VAL_t_14_2_3_9,VAL_t_14_2_3_10

Proportion of Subjects Requiring Anti-VEGF Rescue Through 12 Weeks



Rescue Criteria (Either Triggers Rescue):

- Increase in CST of +75µm from the lowest value (trough)
- Decrease in BCVA of -10 ETDRS letters from the highest value (peak)

VAL_f_14_2_4_1

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Summary of Treatment Emergent Adverse Events

	Sham (%) (N = 33)	UBX1325 10 µg (%) (N = 32)	Overall (%) (N = 65)
Subjects with at least one TEAE	21 (63.6)	20 (62.5)	41 (63.1)
Related TEAE	3 (9.1)	6 (18.8)	9 (13.8)
Grade ≥3 TEAE	3 (9.1)	2 (6.3)	5 (7.7)
Serious TEAE	1 (3.0)	2 (6.3)	3 (4.6)*
Ocular TEAE for Study Eye	17 (51.5)	16 (50.0)	33 (50.8)
Treatment-related Ocular TEAE for Study Eye	3 (9.1)	6 (18.8)	9 (13.8)**
TEAE leading to death	0	0	0
Intraocular inflammation, endophthalmitis, retinal vein occlusion, or vasculitis	0	0	0

Data as of 22 July 2022 or Week 12 visit

* unrelated or likely unrelated to study drug
** most are likely procedural related

Source data: VAL_t_14_3_1_1; VAL_t_14_3_1_2

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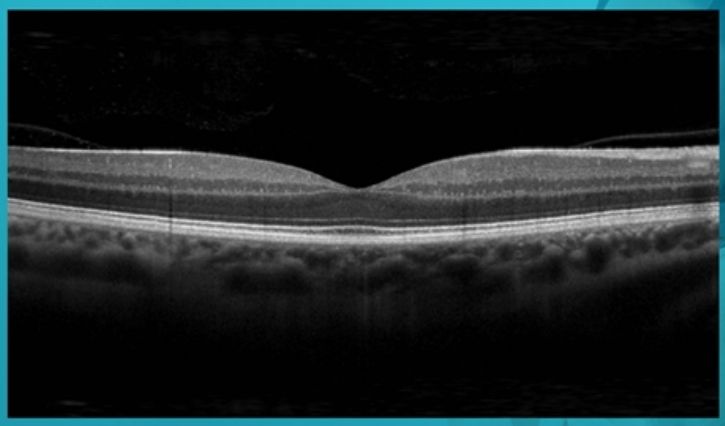
Examples of Imaging Data



Normal Optical Coherence Tomograph (OCT)

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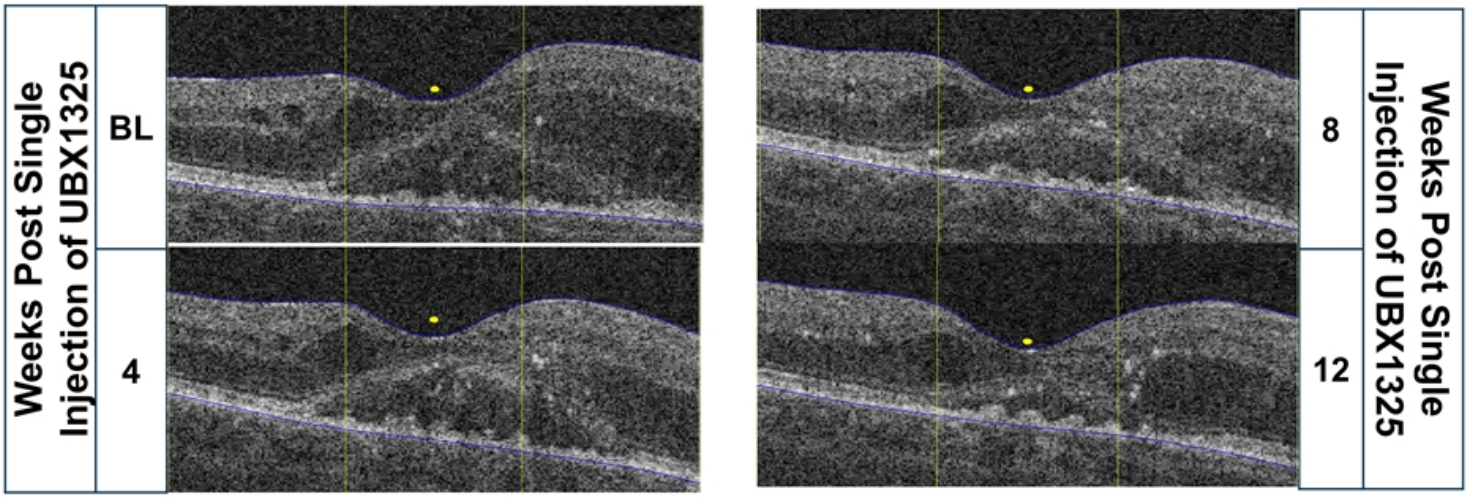
PATIENT A



From Baseline to Week 12:

- Decrease in IRF
- Decrease in SRF
- Decrease in volume
- Decrease in CST ~85 microns

Source: Duke Reading Center Images assessed by an independent unmasked image reader

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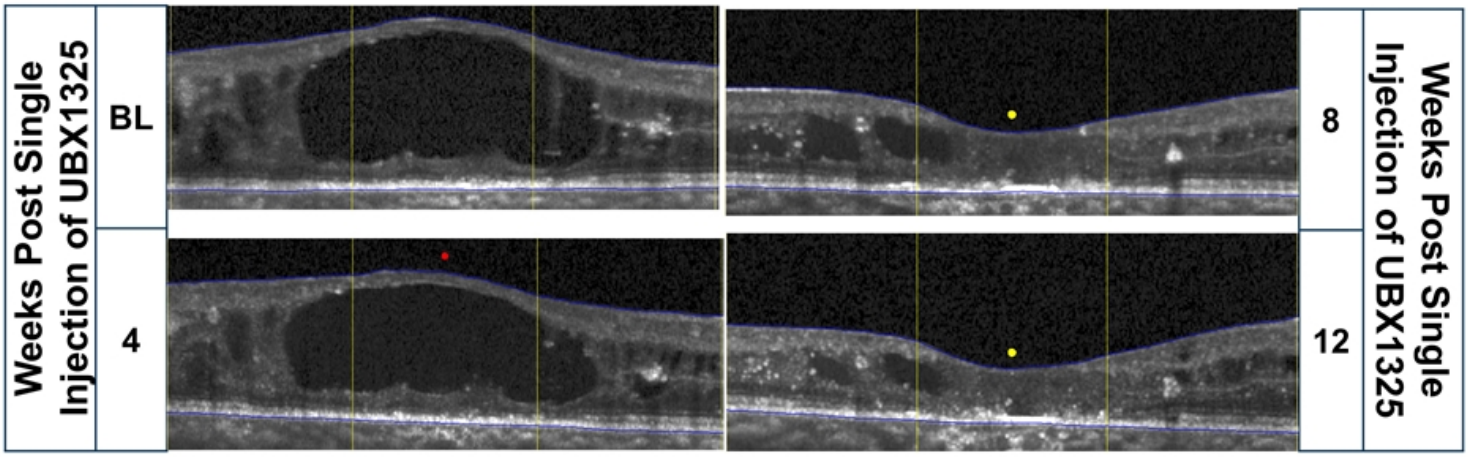
PATIENT B



From Baseline to Week 12:

- Decrease in IRF
- Decrease in volume (mm3) ~10%
- Decrease in CST ~250 microns

Source: Duke Reading Center Images assessed by an independent unmasked image reader

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A Single Injection of UBX1325 Demonstrated Evidence of a Senolytic Agent Improving Visual Acuity in Patients with Diabetic Macular Edema

In the BEHOLD Study, UBX1325:

- Was well tolerated with a favorable safety profile and no intraocular inflammation
- Improved BCVA that was durable through 18-weeks
- BCVA gains were robust across a range of disease severity
- Maintained retinal structure vs. sham-treated subjects

UBX1325 Provides an Opportunity for a Transformative First-in-Class and Best-in-Disease Therapy

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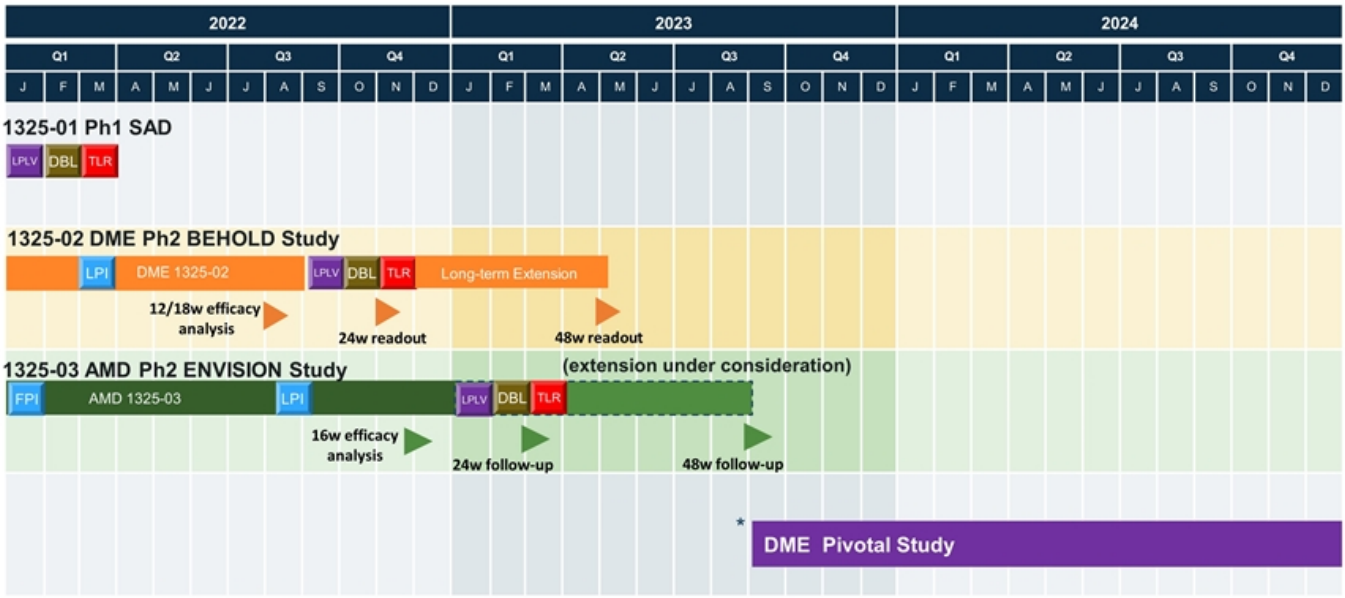
1325 Program Overview and Data Readouts 2022-24

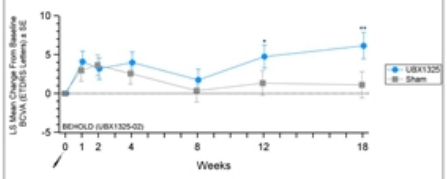


*under consideration, 2H2023

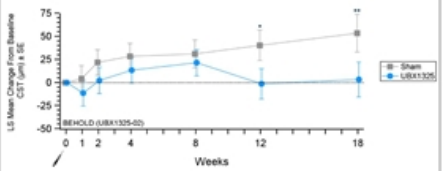
Key Highlights from Phase 2 BEHOLD DME Study

12- and 18-week data underscore the therapeutic potential of UBX1325

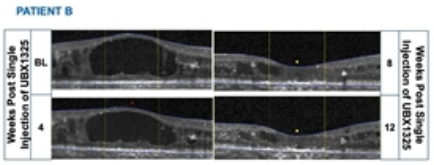
Visual Acuity Improvement



Control of Macular Edema



Impact on Retinal Structure



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