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): April 24, 2023

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, California** **(Address of Principal Executive Offices)**	**94080** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 416-1192

(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 $0.0001 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 April 24, 2023, Unity Biotechnology, Inc. ("UNITY" or the "Company") announced positive 48-week data from its Phase 2 BEHOLD study of UBX1325 in patients with diabetic macular edema (DME). The Company will host a conference call today, Monday, April 24, 2023, 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 48-Week Results from Phase 2 BEHOLD Study of UBX1325 in Patients with Diabetic Macular Edema," dated April 24, 2023
99.2	Presentation of Unity Biotechnology, Inc. dated April 24, 2023
104	Cover Page Interactive Data File (embedded within 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.

UNITY BIOTECHNOLOGY, INC.

Date: April 24, 2023

By: /s/ Anirvan Ghosh

Anirvan Ghosh, Ph.D.
Chief Executive Officer

UNITY
BIOTECHNOLOGY

UNITY Biotechnology Announces Positive 48-Week Results from Phase 2 BEHOLD Study of UBX1325 in Patients with Diabetic Macular Edema

A single injection of UBX1325 led to a statistically significant and clinically meaningful improvement in Best Corrected Visual Acuity (BCVA) of +6.2 ETDRS letters from baseline at 48 weeks

Approximately 53% of UBX1325-treated patients did not require any additional injections through 48 weeks

Retinal structure, as measured by central subfield thickness (CST), was maintained in UBX1325-treated patients throughout the duration of the study

UBX1325 had a favorable safety and tolerability profile with no evidence of intraocular inflammation

UNITY to host investor call with retinal expert
Robert B. Bhisitkul, M.D., Ph.D., today, April 24 at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., April 24, 2023 – UNITY Biotechnology, Inc. ("UNITY") [Nasdaq: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced positive results from the long-term follow-up of the Phase 2 BEHOLD study of UBX1325 in patients with diabetic macular edema (DME). A single injection of UBX1325 treatment led to a statistically significant improvement in vision lasting for the duration of the study (48 weeks), marked by a gain of +6.2 ETDRS letters from baseline, representing a difference of +5.6 ETDRS letters compared to sham-treated patients. In addition, patients treated with UBX1325 maintained stable CST compared to worsening in sham-treated patients.

"This is a defining moment for the senolytic therapeutic hypothesis and is a pivotal moment for UNITY. Achieving sustained improvements in visual acuity and stabilization of retinal structure for almost 1 year after a single injection of UBX1325 is a remarkable result," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "UBX1325 is the only treatment candidate in clinical development that targets senescent cells to potentially modify the course of disease, and this therapeutic approach could redefine the standard of care in DME. Based on the strong emerging clinical profile of UBX1325, we are planning to move forward with our Phase 2b DME head-to-head study against aflibercept in the second half of 2023."

The BEHOLD study enrolled patients who, despite being on anti-VEGF treatment for at least 6 months, displayed persistent visual acuity deficits and residual retinal fluid. At baseline, patients in the study had an average visual acuity of 61.4 ETDRS letters and a CST of approximately 439.6 microns. In the 6 months prior to study enrollment, patients received an average of 4 anti-VEGF injections, with the last anti-VEGF injection occurring 3-6 weeks prior to randomization. Fifty patients completed the 48-week study extension.

48-Week Phase 2 BEHOLD Data:

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

- Patients treated with UBX1325 had a mean change in BCVA of +6.2 ETDRS letters from baseline to 48 weeks (p=0.0037), representing a difference of +5.6 ETDRS letters compared to sham-treated patients (p=0.1198)

- Based on an analysis of the BCVA change from baseline to last observation before anti-VEGF rescue or end of study participation, UBX1325 showed a +7.6 ETDRS letter advantage over sham (p = 0.0007)

- Approximately 53% of UBX1325-treated patients went 48 weeks without requiring any anti-VEGF rescue treatment compared to only 22% of patients in the sham arm

- Patients treated with UBX1325 had a mean change in CST of -16.6 microns from baseline at 40 weeks, representing an improvement compared to sham of -56.3 microns (p = 0.0479); at 48 weeks, UBX1325 had a mean change of -13.7 microns representing an improvement of -37.9 microns compared to sham (p = NS, in part due to the low number of sham patients remaining rescue-free at 48 weeks).

“DME patients are challenging to treat, often requiring frequent injections to decrease retinal edema and improve or even maintain vision. In this study, UBX1325 achieved visual improvement with a single injection, and maintained this improvement in over 50% of patients for a year,” said Jeffrey S. Heier, M.D., Director of Retina Research at Ophthalmic Consultants of Boston. “UBX1325, with a novel mechanism of action, could be an important therapeutic option for patients with such a complex, multifactorial disease.”

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. Robert B. Bhisitkul, M.D., Ph.D., of University of California San Francisco School of Medicine, as well as members of the UNITY senior management team will lead the discussion on the 48-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 the BEHOLD Study

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 through 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 ≥300 microns). Patients had the option of continuing in the long-term extension portion of the study through 48-weeks, in which the majority of patients had opted to remain in the study. More information about the study is available here (NCT04857996).

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 the 24-week data of the Phase 2 BEHOLD study in patients with DME, a single injection of UBX1325 led to a statistically significant and clinically meaningful improvement in mean Best Corrected Visual Acuity (BCVA) at 24 weeks compared to sham treatment.

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 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, UNITY's 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 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, 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 Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 15, 2023, 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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UBX1325
Phase 2 BEHOLD Study in DME
48 Week Top Line Results

NASDAQ: UBX

24 April 2023

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, UNITY's 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 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 presentation 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 Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 15, 2023, 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.

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Top Line Results

UBX1325 Mechanism of Action

Clinical Development Plan

UBX1325 Led to a Statistically Significant and Clinically Meaningful Improvement in Visual Acuity in Patients with Diabetic Macular Edema Through 48 Weeks

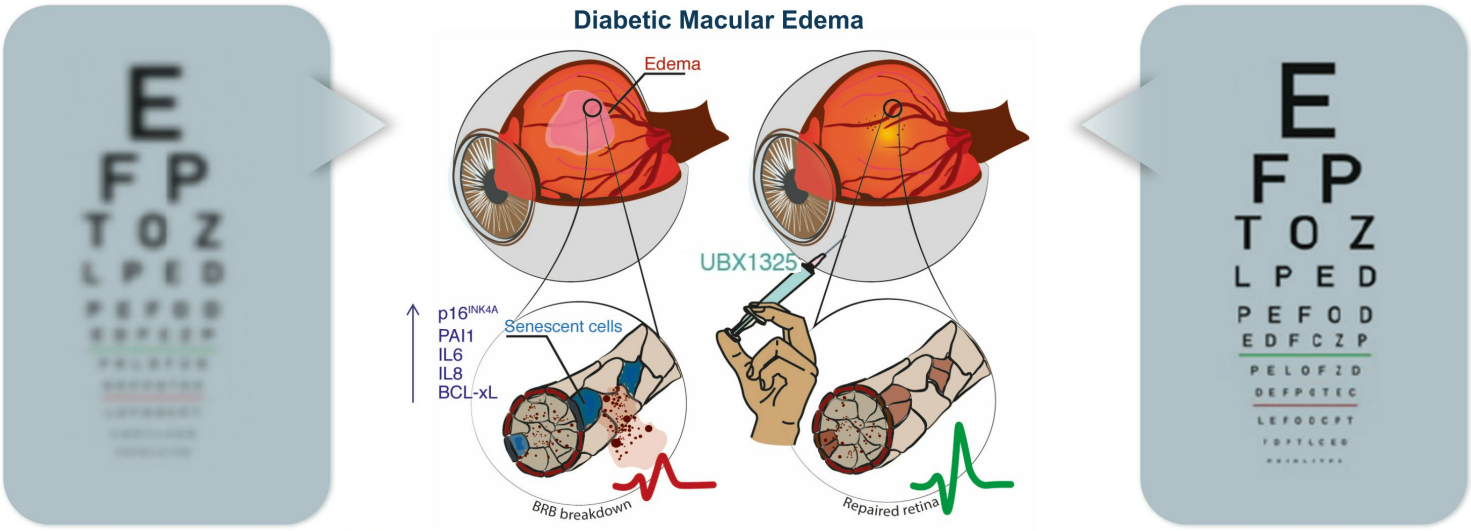
Phase 2 BEHOLD Study Data Highlights

A **single dose of UBX1325** demonstrated:

- UBX1325-treated patients had **a significant improvement in BCVA** of +6.2 ETDRS letters from baseline and +5.6 ETDRS letters compared to sham at 48 weeks
- Approximately **53% of UBX1325-treated patients did not require any additional injections** through 48 weeks
- There was more than a **30-week difference in median time-to-first-rescue** favoring UBX1325 over sham
- **Retinal structure was maintained** in UBX1325-treated patients with a central subfield thickness that was lower than baseline and was -37.9 µm compared to sham at 48 weeks
- UBX1325 had a **favorable safety and tolerability profile** with no evidence of intraocular inflammation

UBX1325 may be an important future therapeutic option for patients with diabetic macular edema

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



DME:

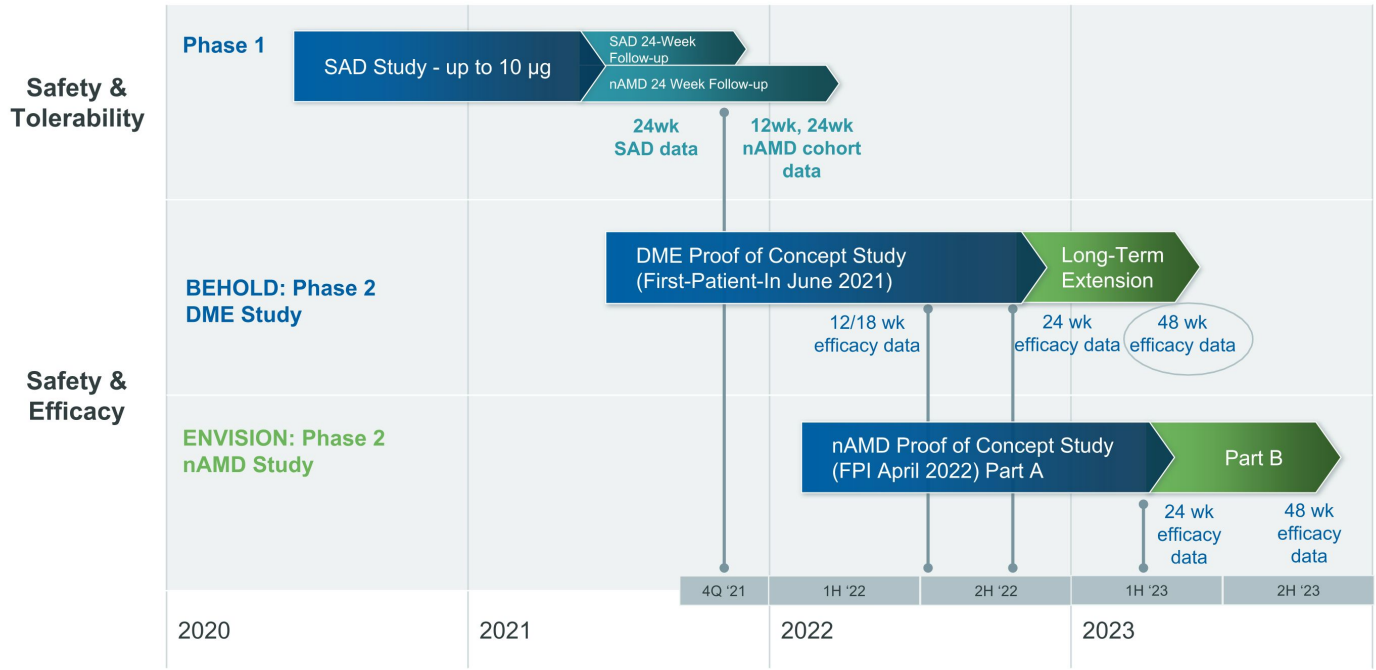
- Increased senescence burden
- Poor barrier function
- Production of inflammatory factors
- Loss of retinal function

DME treated with Senolytic (intended results):

- Senescent cells removed
- Barrier function improved
- Inflammatory factors reduced
- Sustained improvement in retinal function

UNITY illustration

UBX1325 Clinical Program Overview



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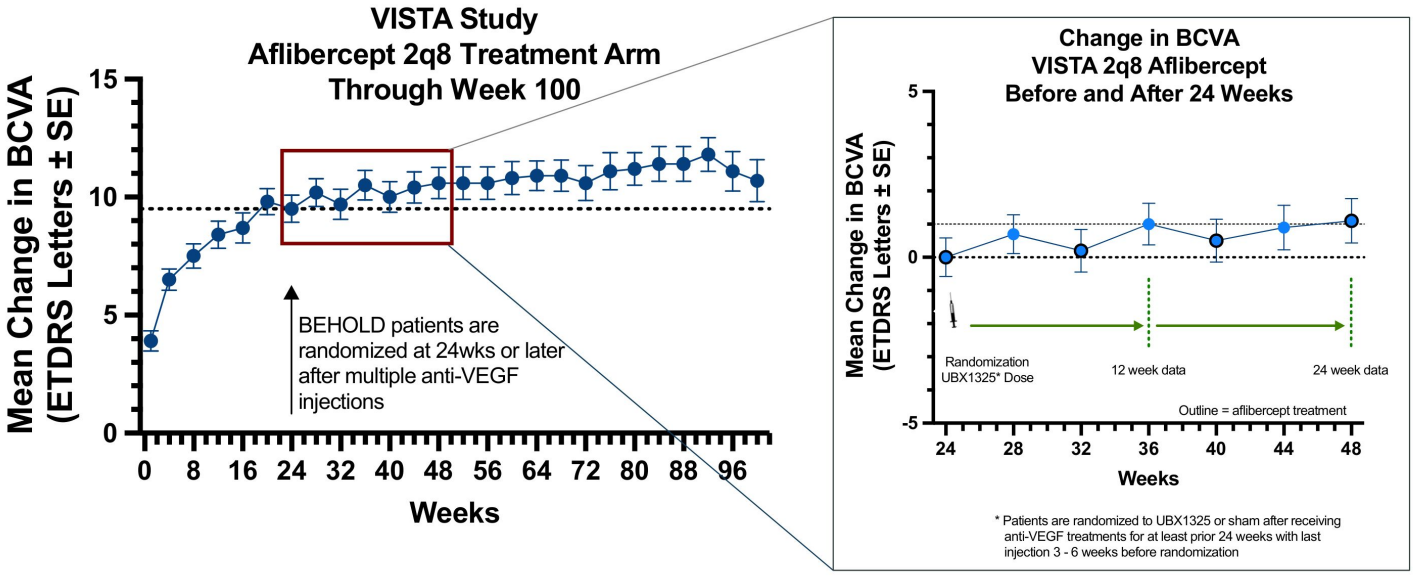
Context for 24wk DME Data: After Anti-VEGF Effect Has Plateaued, Patients Gain Approximately 1 Letter in Subsequent 6 Months on Aflibercept Treatment



VISTA BLA 125387 Suppl 48, 25 Mar 2015

UBX1325 Ph2 BEHOLD Study

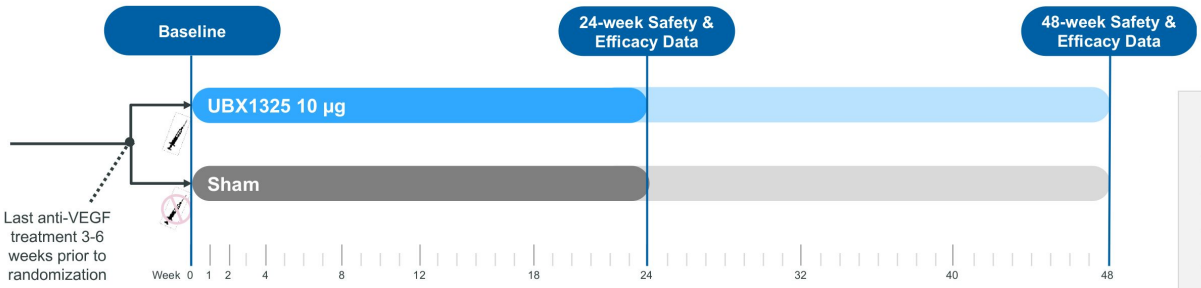
48-week data in patients with DME

BEHOLD Study Design, Patient Population, and Endpoints

Patient Population

Individuals with **Diabetic Macular Edema**

- **Repeated anti-VEGF** treatments (≥2 injections/6 months) – Actual: 4.1 injections in prior 6 months
- **Residual retinal fluid** (≥300 µm) – Actual: 439.6 µm
- **Visual acuity deficit** (73 ETDRS letters or worse) – Actual: 61.4 ETDRS letters



	Sham	UBX	Total
Full Analysis Set	33	32	65
Completed to 24 Weeks only	4	5	9
Lost to follow-up	1	3	4
Site Closure	1	0	1
Patient withdrawal	1	0	1
Available through 48 Weeks	26	24	50

= UBX1325 injection

= Sham injection

Endpoints

- Safety and tolerability
- BCVA change from baseline
- Durability of response
- Sub- and intra-retinal fluid, CST changes
- Proportion of UBX1325 patients requiring 2 or more rescue treatments

Source: t_14_1_1

Patient characteristics at baseline were well balanced between groups

Parameter, Units (SD)	Sham	UBX1325
Age, Years	61.4 (9.09)	63.6 (9.33)
HBA1c, %	7.4 (1.36)	8.0 (1.68)
Diabetes Dx, Years	17.5 (10.53)	17.2 (11.41)
DME Dx, Years	3.0 (2.32)	3.5 (3.60)
BCVA, ETDRS letters	61.8 (9.61)	60.9 (9.97)
CST, µm	456.2 (98.07)	422.5 (84.16)
Anti VEGF prior 190 days		
Afilbercept	13	13
Aflibercept, bevacizumab	4	1
Bevacizumab	15	16
Ranibizumab	1	2

Balanced on other parameters at baseline: ethnicity & race, BMI, DRSS score

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Source: t_14_1_2

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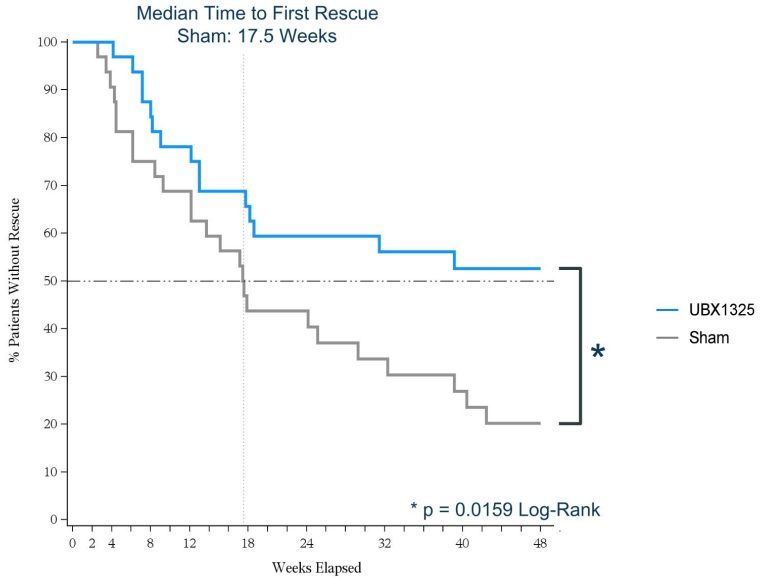
UBX1325-treated patients had marked drop in need for anti-VEGF rescue beyond week 18 compared to Sham-treated patients through 48 weeks

- Median Time-To-First-Rescue in UBX arm was >48 weeks (at least 30 weeks greater than Sham arm)
- ~53% of UBX-treated patients went without rescue through 48 weeks
- ~80% of sham-treated patients required rescue before 48 weeks

Rescue Criteria (Either)

- Decrease of 10 ETDRS or more letters from any peak value
- Increase in CST of 75 µm or more from baseline



Efficacy analyses *excluding* and *including* data post anti-VEGF rescue show a treatment benefit of UBX1325

24 April 2023

Source: f_km_plots_listings; f_km_plots

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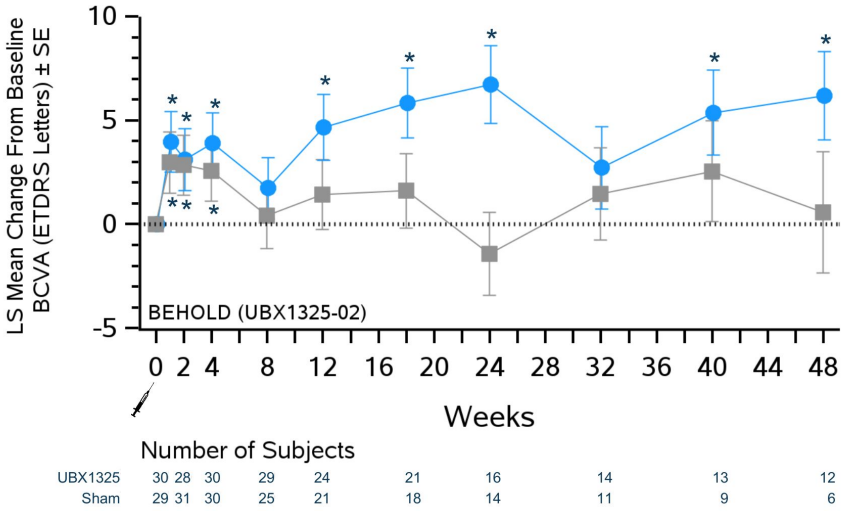
UBX1325-treated patients had a significant improvement in BCVA from baseline† of 6.2 letters at 48 weeks (*excluding* data post-rescue)



Number of Subjects

UBX1325	30	28	30	29	24	21	16	14	13	12
Sham	29	31	30	25	21	18	14	11	9	6

BCVA CFBL (ETDRS Letters)	UBX1325	Sham	Delta	Between Group p-value
Week 24	6.7	-1.4	8.1	0.0031
CFBL p-value	0.0004	NS		
Week 48	6.2	0.6	5.6	0.1198
CFBL p-value	0.0037	NS		

NS: not significant

† MMRM Analysis

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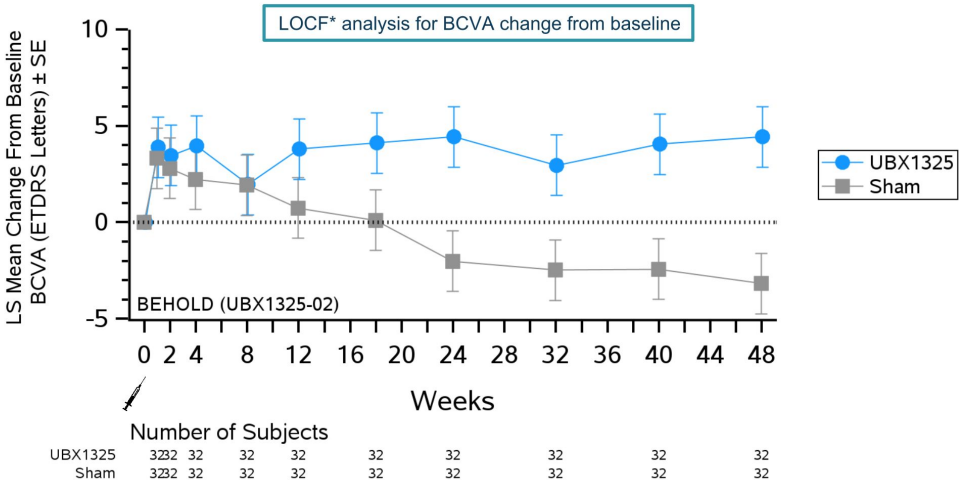
Source: f_14_2_1_1; t_14_2_1_1

UBX1325-treated patients had significant visual acuity gains compared to Sham based on analysis of last observation prior to rescue or end of study†

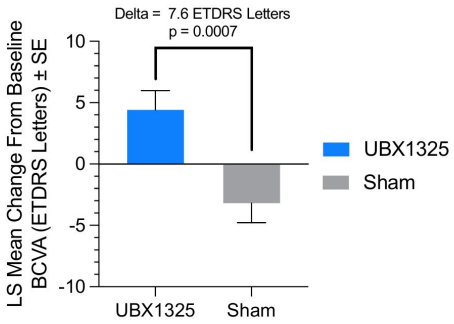
LOCF* analysis for BCVA change from baseline



Number of Subjects

UBX1325	32	32	32	32	32	32	32	32	32	32
Sham	32	32	32	32	32	32	32	32	32	32

Mean BCVA change from baseline to last observation



* Last observation carried forward (to rescue or end of study participation)

† Supplemental Analysis

24 April 2023

Source: f_14_2_1_35

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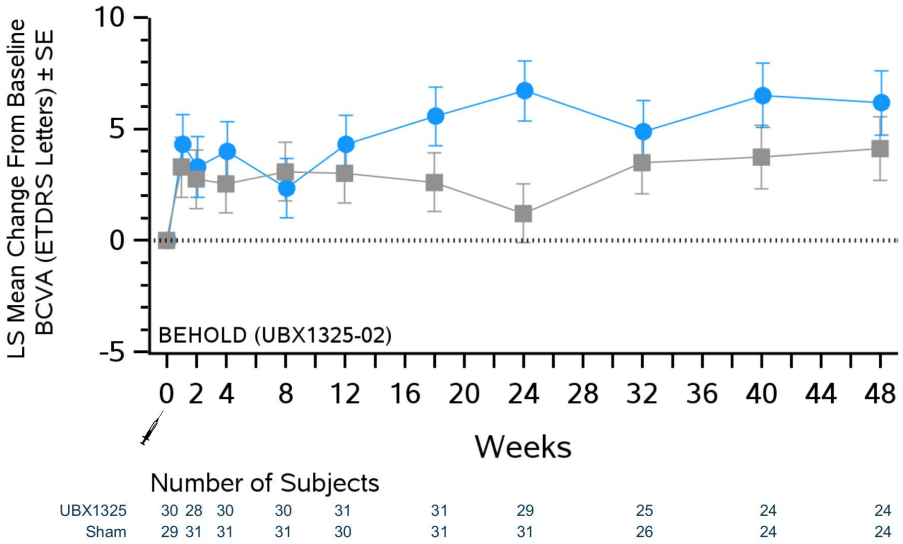
At all timepoints, UBX1325-treated patients had a statistically significant improvement in BCVA from baseline† (*including* post-rescue data)



Number of Subjects

UBX1325	30	28	30	30	31	31	29	25	24	24
Sham	29	31	31	31	30	31	31	26	24	24

All points p < 0.05 vs. baseline *except* Sham Weeks 4, 24 and UBX Week 8

UBX1325
Sham

BCVA CFBL (ETDRS Letters)	UBX1325	Sham	Delta	Between Group p-value
Week 24	6.7	1.2	5.5	0.0036
CFBL p-value	<0.0001	NS		
Week 48	6.2	4.1	2.0	NS
CFBL p-value	<0.0001	0.0042		

NS: not significant

† MMRM Analysis

24 April 2023

Source: f_14_2_1_13; t_14_2_1_2

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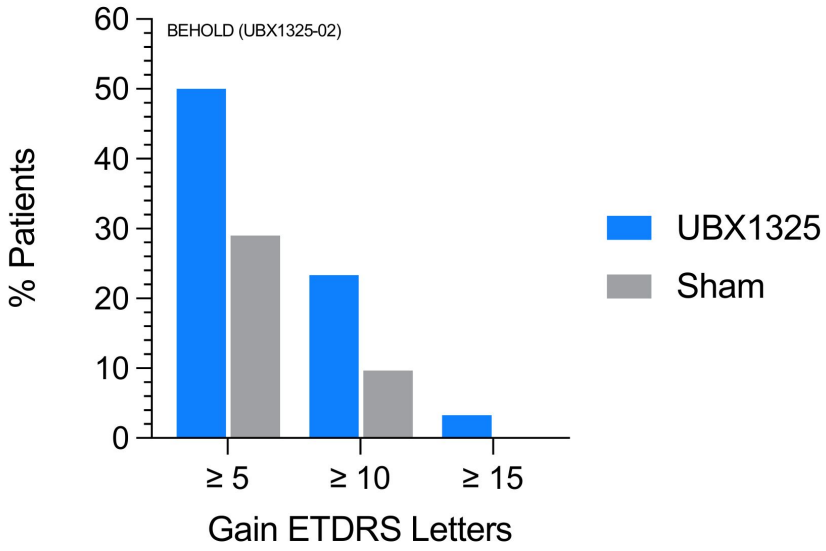
50% of UBX1325-treated patients gained at least 5 letters of vision through 48 weeks, with over 20% gaining at least 10 letters (*excluding* post-rescue data)



24 April 2023

Source: t_14_2_4_1

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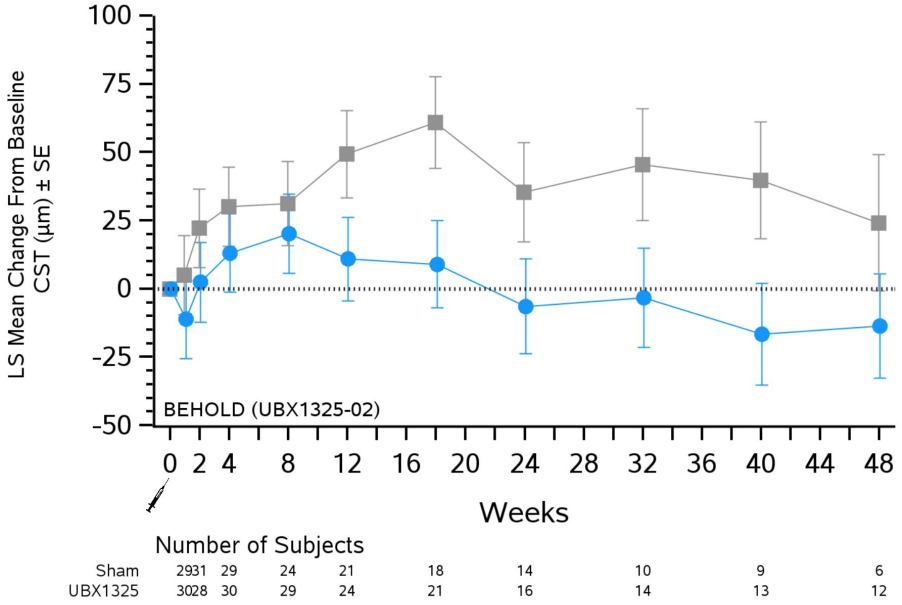
CST remained stable in UBX1325-treated patients compared to worsening in Sham patients (*excluding* post-rescue data)



Sham: p < 0.15 vs BL all points *except* Weeks 1 and 48
UBX: All points not significantly different from baseline

Sham
UBX1325

BCVA CFBL (ETDRS Letters)	UBX1325	Sham	Delta	Between Group p-value
Week 24	-6.4	35.4	-41.8	0.0985
CFBL p-value	NS	0.0534		
Week 48	-13.7	24.2	-37.9	NS
CFBL p-value	NS	NS		

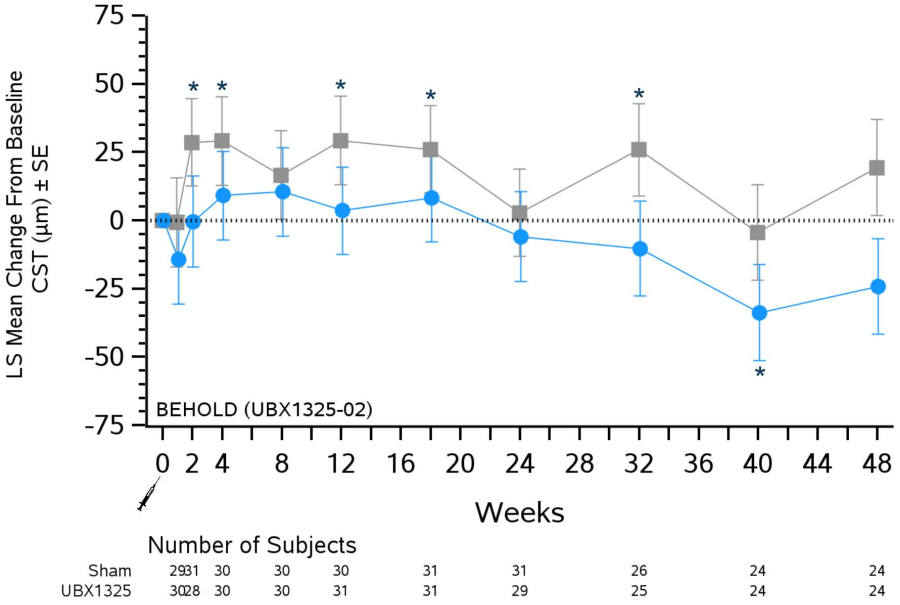
NS: not significant

24 April 2023

Source: f_14_2_1_2; t_14_2_1_3

UNITY BIOTECHNOLOGY

Mean CST was significantly lower in UBX1325-treated patients compared to Sham patients at 48 weeks (*including* post-rescue data)



Number of Subjects

Sham	29	31	30	30	30	31	31	26	24	24
UBX1325	30	28	30	30	31	31	29	25	24	24

BCVA CFBL (ETDRS Letters)	UBX1325	Sham	Delta	Between Group p-value
Week 24	-5.9	2.8	-8.7	NS
CFBL p-value	NS	NS		
Week 48	-24.2	19.4	-43.6	0.0794
CFBL p-value	NS	NS		

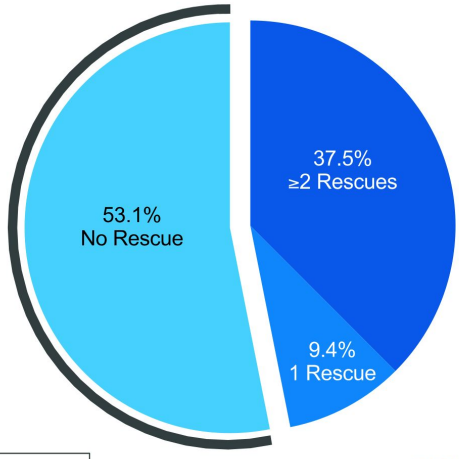
NS: not significant

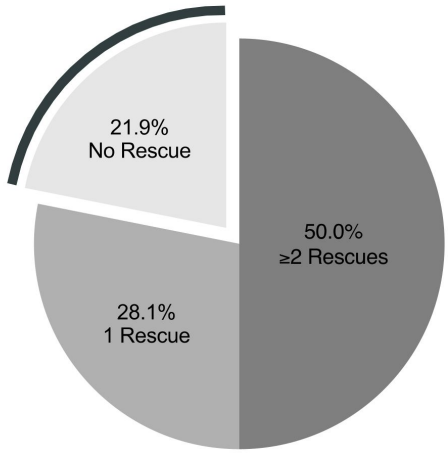
24 April 2023

Source: f_14_2_1_14; t_14_2_1_4

UNITY BIOTECHNOLOGY

53.1% of UBX1325-treated patients did not require anti-VEGF rescue through 48 weeks compared to 21.9% of Sham patients





Rescue Criteria (Either)

- Decrease of 10 ETDRS or more letters from any peak value
- Increase in CST of 75 µm or more from baseline

n = 32
UBX1325

UBX vs. Sham
p = 0.0096

n = 32
Sham

Source: f_14_2_4_1; t_14_2_2_1

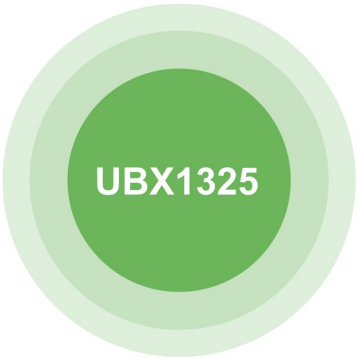
UBX1325 demonstrated a favorable overall safety and tolerability profile with no instances of intraocular inflammation

Parameter, No. of Patients	Sham (N = 33)	UBX1325 10 µg (N = 32)
Subjects with at least one TEAE	31 (93.9)	26 (81.3)
Related TEAE	3 (9.1)	6 (18.8)
Grade >=3 TEAE	4 (12.1)	5 (15.6)
Serious TEAE	3 (9.1)	5 (15.6)
Ocular TEAE for Study Eye	28 (84.8)	23 (71.9)
Treatment-related Ocular TEAE for Study Eye	3 (9.1)*	6 (18.8)*
TEAE leading to death	0	0
Intraocular inflammation, endophthalmitis, retinal artery occlusion, or vasculitis	**0**	**0**

* Most are likely procedural related, all were mild-mod, and self-limited:
Sham: 1 conj. hemorrhage, 1 conj. hyperemia, 1 diabetic macular edema
UBX: 5 conj. hemorrhage, 1 ant. chamber pigmentation, 1 eye irritation

Source: t_14_3_1_1

Summary of Findings and Concordance of Evidence Supporting a Treatment Effect of UBX1325 in Diabetic Macular Edema



In the BEHOLD Study, UBX1325:

- Improved visual acuity at 48 weeks by **6.2 letters from baseline after a single injection**
- Led to a majority of patients achieving a **rescue-free interval of at least 48 weeks** and may represent the **potential for disease modification**
- **Maintained retinal structure** throughout the duration of the study without the need for anti-VEGF rescue
- Had a **generally favorable safety and tolerability profile** with no intraocular inflammation

UBX1325 may be an important future therapeutic option for patients with diabetic macular edema

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Q&A