UNITY Biotechnology Completes Enrollment in Phase 2 ENVISION Study of UBX1325 in Wet Age-related Macular Degeneration

September 19, 2022

Enrollment of 51 patients exceeds target by ~10% due to high interest in the study

16-week data anticipated in Q1 2023 and 24-week data anticipated in Q2 2023

SOUTH SAN FRANCISCO, Calif., Sept. 19, 2022 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. ("UNITY") [NASDAQ: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, has completed enrollment for the ENVISION study, its Phase 2 clinical trial of UBX1325 in patients with wet age-related macular degeneration (AMD). This is an active comparator study, examining the efficacy of two doses of UBX1325 compared to every other month treatment with aflibercept through 24 weeks.

"Completion of enrollment of the ENVISION study is an important milestone for UNITY and illustrates the momentum and interest in the program as we continue to explore indications where UBX1325 could provide benefit beyond current standard of care," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "UBX1325 is a first in class senolytic agent being studied as a treatment for retinal disease. Following the initial evidence of a treatment effect of UBX1325 in patients with diabetic macular edema (DME), we are excited to assess the safety and efficacy of UBX1325 in patients with wet AMD."

Dr. Ghosh added: "We have a number of critical data readouts over the next three quarters, and a cash runway that extends into 2024. Our next major milestone is the 24-week data from the BEHOLD study in DME, expected by end of year 2022, followed by 48-week results in the second quarter of 2023. In the ENVISION study we expect 16-week data in the first quarter of 2023, with 24-week data to follow in the second quarter of 2023. We look forward to sharing data from these studies in the months to come."

About the Phase 2 ENVISION study in wet AMD

ENVISION is a multi-center, randomized, active comparator-controlled, double-masked Phase 2 study designed to evaluate the safety, tolerability, efficacy, and durability of UBX1325 in patients with wet AMD. Patients are randomized into one of two study arms – patients receive either A) two doses of UBX1325 (10 mcg) at week 0 and week 4, or B) aflibercept (2 mcg) every eight weeks for a total of four injections. Outcome measures include safety and tolerability, average change in BCVA from baseline at 16 and 24 weeks as well as change in CST from baseline at 16 and 24 weeks.

More information about the study is available at www.clinicaltrials.gov (NCT05275205), or view our latest corporate presentation on our website here.

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 Phase 2 BEHOLD study in patients with DME, 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. 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 – including improved vision, a longer more durable effect, and lower frequency of treatment – 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 the clinical trials in 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 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.

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