UNITY Biotechnology Doses First Patient in ENVISION, the Phase 2 Study of UBX1325 in Wet Age-Related Macular Degeneration

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16-week results from Phase 2 study in wet AMD expected in Q4 2022

SOUTH SAN FRANCISCO, Calif., April 19, 2022 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. (“UNITY”) [NASDAQ: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced that the first patient has been dosed in the ENVISION study, its Phase 2 clinical trial of UBX1325 in patients with wet age-related macular degeneration (wAMD).

“The clinical and preclinical data generated so far suggests that UBX1325, a senolytic small molecule with disease-modifying potential, could improve retinal function through an entirely novel pathway,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “The Phase 2 study enables us to further explore whether UBX1325 may provide improved treatment options for patients with wAMD in parallel with our ongoing Phase 2 study, BEHOLD, in diabetic macular edema. We continue to advance our ophthalmology programs, with a sharpened focus into the next stage of development and remain on track to announce data from both studies over the course of the year.”

The Phase 2 trial in wAMD, ENVISION, is a multi-center, randomized, active comparator controlled, double-masked study designed to evaluate the safety, tolerability, efficacy, and durability of UBX1325 in patients with wAMD. The study is actively recruiting patients and is targeted to enroll 46 patients with wAMD, who will be randomized to receive either two doses of UBX1325 (10 mcg) at week 0 and week 4, or aflibercept (2 mcg) every eight weeks. The Company expects 16-week safety and efficacy results from the ongoing study in the fourth quarter of 2022. More information about the study is available here (NCT05275205).

“Encouraged by the clinical data generated in the Phase 1 study, in which the majority of patients treated with a single dose of UBX1325 showed an increase in visual acuity at 24 weeks, the Phase 2 wAMD ENVISION study will compare UBX1325 administered in a repeat dose regimen to standard-of-care aflibercept in patients with early persistent retinal fluid and visual acuity deficits,” said Jamie Dananberg, M.D., chief medical officer of UNITY. “As the first senolytic treatment being explored for retinovascular diseases, we believe UBX1325 may improve visual function and lessen the significant treatment burden imposed on patients through a biological pathway distinct from, but complementary to, anti-VEGF treatment.”

About UBX1325

UBX1325 is an investigational compound being studied for age-related diseases of the eye, including diabetic macular edema (DME), wet age-related macular degeneration (wAMD), 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 preclinical studies, UNITY has demonstrated that targeting Bcl-xL with UBX1325 preferentially eliminated senescent cells from diseased tissue while sparing cells in healthy tissue. UBX1325 has shown a favorable safety profile and improvements in visual acuity sustained through 24 weeks following a single dose in a Phase 1 clinical study in advanced vascular eye disease. 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 of results of our studies of UBX1325, 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 Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 15, 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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