UNITY Biotechnology Completes Enrollment in BEHOLD, the Phase 2 Study of Senolytic Candidate UBX1325 in Diabetic Macular Edema

April 12, 2022

12-week safety and efficacy data anticipated by mid-year 2022

24-week safety and efficacy data anticipated before year-end 2022

SOUTH SAN FRANCISCO, Calif., April 12, 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 BEHOLD study, its Phase 2 clinical trial of UBX1325 in patients with diabetic macular edema (DME).

“Patients with advanced retinovascular diseases, including DME, shoulder a significant burden with current standard-of-care that usually requires regular doctor visits for frequent injections of anti-VEGF treatment, often as frequently as every 8 weeks,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “Given the encouraging activity we’ve observed in patients with DME after a single injection of UBX1325 in our Phase 1 study in patients no longer considered responsive to anti-VEGF treatment, we’re optimistic that UBX1325 can potentially provide an entirely novel therapeutic option and lessen the current burden on both patients and physicians as a durable senolytic treatment. We are very pleased to have completed enrollment and see this as a significant milestone in the UBX1325 clinical program. We look forward to building on this momentum and anticipate 12-week results from our Phase 2 DME study, BEHOLD, by mid-year and 24-week results by the end of the year.”

The proof-of-concept Phase 2 study, BEHOLD, 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. The study enrolled 65 patients who will be followed for up to approximately 48 weeks. More information about the study is available here (NCT 04857996). In parallel, a separate Phase 2 study of UBX1325 in wet age-related macular degeneration is currently enrolling patients, with 16-week results anticipated by year-end 2022. More information about the study is available here (NCT05275205).

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 vascular eye disease, UBX1325 has shown a favorable safety profile and improvements in visual acuity sustained through 24 weeks following a single dose. 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 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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