UNITY Biotechnology Announces Improvement in Visual Acuity Sustained Through 24 Weeks Following Single Dose of UBX1325 in Phase 1 Study of Patients with Advanced Vascular Eye Disease

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Patients with diabetic macular edema in higher dose cohorts showed a mean BCVA gain of approximately 10 ETDRS letters sustained through 24 weeks after a single intravitreal injection

Patients with wet age-related macular degeneration showed improvement in visual acuity through 12 weeks supporting initiation of Phase 2 study in AMD

UNITY to host investor call with retinal experts Arshad Khanani, M.D., M.A., and Robert Bhisitkul, M.D., Ph.D., today, November 9, 2021 at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2021 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. (“UNITY”) [NASDAQ: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced 24-week data from its Phase 1 single ascending dose (SAD) safety study of UBX1325 in patients with advanced disease from diabetic macular edema (DME) or wet age-related macular degeneration (AMD). A majority of patients with DME across all doses had rapid improvements in vision, and patients in the higher dose cohorts showed a mean gain of 9.5 ETDRS letters in best-corrected visual acuity (BCVA) at 24 weeks following a single injection of UBX1325. Similarly, a majority of wet AMD patients treated with UBX1325 showed rapid gains in visual acuity, which were maintained through 12 weeks. In most patients, central subfield thickness (CST) remained stable through the study period.

UBX1325 Well-Tolerated at All Doses
The study enrolled a total of 19 patients with advanced DME (n=8) and wet AMD (n=11) for whom anti-VEGF therapy was no longer considered beneficial. UBX1325 was well-tolerated at all doses tested (through 10 mcg) with no dose-limiting toxicities and no reported incidence of inflammation.

Results from Patients with Diabetic Macular Edema Treated with UBX1325
The Phase 1 data show rapid improvements in visual acuity as measured by BCVA in patients with DME, with the majority of patients demonstrating sustained responses through 24 weeks:

- • Across all DME patients enrolled (n=8), there was an improvement in visual acuity in 6 of 8 patients at 12 weeks, and in 5 of 8 patients at 24 weeks
- • In the higher dose cohorts (5, 10 mcg), patients had a mean improvement of 9.5 ETDRS letters from baseline at 24 weeks
- • Amongst all DME patients, 62.5% gained 5 or more letters at 24 weeks, and 50% gained 10 or more letters also at 24 weeks
- • In the majority of patients with DME, CST remained stable through 24 weeks

“A 10 letter gain in DME patients, maintained through six months, is an impressive outcome, and is particularly noteworthy considering that it was achieved with a single injection,” said Arshad Khanani, M.D., M.A., managing partner of Sierra Eye Associates. “Hard-to-treat patients require as many as 10 injections in the first year of treatment to see full benefits from currently available anti-VEGF therapies. A treatment that reduces the frequency of injections while showing meaningful and sustained improvements in BCVA would be of huge value for patients and physicians.”

Results from Patients with Wet Age-Related Macular Degeneration Treated with UBX1325
The Phase 1 study included 11 wet AMD patients (4 in the SAD cohort, and an additional 7 in an expansion cohort). A majority of patients showed rapid improvements in visual acuity:

- • Across all evaluable patients with wet AMD enrolled (10 of 11), there was an improvement in visual acuity in 7 of 10 patients at 8 weeks, and in 5 of 10 patients at 12 weeks
- • 2 of 3 patients in the SAD cohort maintained their visual acuity gain through 24 weeks
- • Within the ten evaluable patients with wet AMD, CST remained stable through 12 weeks; this trend was also observed in the three evaluable patients with wet AMD at 24 weeks, and 2 of those 3 patients showed resolution of most subretinal fluid

“Patients with wet AMD will lose vision without treatment and have a worse prognosis than patients with DME, which is why the letter gain seen in the AMD cohort is so meaningful,” said Robert Bhisitkul, M.D., Ph.D., professor of ophthalmology and director of the Retina Fellowship at University of California, San Francisco. “The efficacy that we are seeing in AMD patients provides a convincing rationale for advancing this program into additional clinical studies.”

“We have now followed advanced DME and AMD patients for 24 weeks, and see clear evidence of rapid and sustained responses from a single

injection of UBX1325," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "The improvements in vision and retinal structure suggest that this new mechanism of action – the selective elimination of senescent cells in diseased retinal tissue – has the potential for disease-modifying effect in a large proportion of patients struggling to manage their disease."

UNITY's Phase 2 study of UBX1325 in DME is underway, with 12-week safety and efficacy data anticipated in the first half of 2022. A Phase 2 study in wet AMD is planned for the first half of 2022, with 12-week data expected in the second half of the year.

Investor Conference Call at 8:00 a.m. ET Today
UNITY will host a video conference call and webcast for investors and analysts on Tuesday, November 9 at 8:00 a.m. ET to discuss the most recent UBX1325 clinical data. Drs. Khanani and Bhisitkul, as well as members of the UNITY senior management team will lead the discussion on the 24-week DME and 12-week wet AMD 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 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 recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, filed with the Securities and Exchange Commission on August 10, 2021, 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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