UNITY Biotechnology Announces Positive 12-Week Data from Phase 1 Clinical Trial of UBX1325 in Advanced Vascular Eye Disease

October 5, 2021

Evidence of improvement in vision and retinal structure in patients with DME and AMD sustained through 12 weeks

Sustained responses following single treatment with UBX1325 support durability of senolytic therapeutic approach; data builds on previously reported results at 8 weeks

Study remains on track with 24-week data expected before the end of the year

UNITY to host investor call with retinal expert Robert Bhisitkul, M.D., Ph.D., on October 5, 2021 at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif., Oct. 05, 2021 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. (“UNITY”) [NASDAQ: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced 12-week data from its ongoing Phase 1 safety study of UBX1325 in patients with advanced disease from diabetic macular edema (DME) and wet age-related macular degeneration (AMD) for whom anti-VEGF therapy was no longer considered beneficial. The data show strong and sustained responses following a single injection of UBX1325 out to 12 weeks and add substantively to the previously reported 8-week dataset, which provided initial evidence of efficacy. The 24-week data from the study is expected before the end of the year.

UBX1325, a small molecule inhibitor of Bcl-xL and the first senolytic drug candidate for ophthalmologic diseases targeting a distinctive biologic pathway from anti-VEGF therapies, continues to be well-tolerated with no treatment-related adverse events or dose-limiting toxicities up to 12 weeks. Additionally, UBX1325 showed sustained responses in key clinical measures of disease progression in most patients through 12 weeks, including substantial improvements in best-corrected visual acuity (BCVA) and central subfield thickness (CST).

“It is promising to see improvements in vision sustained over three months after a single dose in these patients with advanced vascular eye disease, especially considering that these patients had gone at least six months without standard of care anti-VEGF therapy by this point,” said Robert Bhisitkul, M.D., Ph.D., professor of ophthalmology and director of the Retina Fellowship at University of California, San Francisco. “There are limited treatment options for patients who do not benefit from standard of care, so a novel therapeutic approach like UBX1325 could provide significant benefit as an alternative or complement to anti-VEGF treatments.”

Treatment of patients with a single UBX1325 injection resulted in the following clinical changes at 12 weeks following treatment:

Gain in ETDRS Letters from Baseline in Best-Corrected Visual Acuity (BCVA)

- Overall (across all doses): 8 of 12 patients showed a gain in ETDRS letters from baseline in BCVA at 12 weeks
- In high dose groups (5, 10 mcg): 5 of 6 patients showed a gain in ETDRS letters from baseline in BCVA at 12 weeks

Decrease in Central Subfield Thickness (CST)

- Overall (across all doses): 6 of 10 patients had a decrease (improvement) in CST at 12 weeks, excluding two patients who received anti-VEGF rescue therapy following progression of underlying disease
- In high dose groups (5, 10 mcg): 3 of 5 patients showed decrease in CST at 12 weeks, excluding one patient who received anti-VEGF rescue following progression of underlying disease

The Phase 1, open-label, single-ascending dose study includes 12 patients with advanced DME or wet AMD who were no longer expected to benefit from anti-VEGF therapies. Patients enrolled in the study could not have received an anti-VEGF therapy or corticosteroid for three months prior to receiving a single dose of UBX1325. At 12 weeks following treatment with study drug, UBX1325 demonstrated a favorable safety profile supporting further clinical development. There were no dose-limiting toxicities observed, with two nonserious, nondrug-related adverse events reported through 12 weeks.

“We are excited by the trajectory of the data showing both a rapid response and sustained improvements in vision and retinal structure in most patients through 12 weeks following a single injection of UBX1325,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “The consistency of response at 8 and 12 weeks suggests that the functional gains seen to date may be sustained beyond 12 weeks. These data further support our Phase 2a Proof of Concept study in patients with DME, which is already underway, and we anticipate the 12-week safety and efficacy data from that study in the first half 2022.”

UNITY expects to share 8-week data from an additional cohort of patients with wet AMD, as well as complete 24-week data of the original cohort from the Phase 1 single ascending dose study, before the end of the year.

Investor Conference Call at 8:00 a.m. ET Today

UNITY will host a conference call and webcast for investors and analysts on Tuesday, October 5 at 8:00 a.m. ET to discuss the most recent UBX1325 clinical data. Dr. Bhisitkul and members of the UNITY senior management team will lead the discussion on the 12-week data 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. You may also listen to the call by dialing (877) 235-8637 within the U.S. or (704) 815-6400 outside the U.S. and providing conference ID 5226618. 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 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 DR, DME, and AMD.

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.

Media
Canale Communications
Jason Spark
Jason.spark@canalecomm.com

UNITY
BIOTECHNOLOGY

Source: Unity Biotechnology, Inc.