UNITY Biotechnology Announces Positive Data from Phase 1 Clinical Trial of UBX1325 in Patients with Advanced Vascular Eye Disease

July 6, 2021

Improvement in Visual Acuity and Central Subfield Thickness observed in diabetic macular edema (DME) and wet age-related macular degeneration (wet AMD) patients treated with UBX1325

UBX1325 advances to Phase 2a study in DME patients as a potential alternative to anti-VEGF therapies

UNITY to host conference call today at 8:00 a.m. ET

SOUTH SAN FRANCISCO, Calif, July 06, 2021 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. ("UNITY") [NASDAQ: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced positive data from its Phase 1 safety study of UBX1325 in patients with advanced disease from DME or wet AMD for whom anti-VEGF therapy was no longer considered beneficial. UBX1325, a small molecule inhibitor of Bcl-xL and the first senolytic therapeutic evaluated in an ophthalmological clinical study, was well-tolerated with no treatment-related adverse events or dose-limiting toxicities. Additionally, the majority of DME and wet AMD patients treated with a single injection of UBX1325 demonstrated rapid improvements in best-corrected visual acuity (BCVA), central subfield thickness (CST), and sub- and intra-retinal fluid (SRF, IRF), all key clinical measures of disease progression.

The first patient has been dosed in a Phase 2a clinical study to assess the safety and efficacy of UBX1325 in a broader population of patients with DME, and data is expected in the first half of 2022. In addition, UNITY is enrolling additional patients with advanced wet AMD in the Phase 1 study to gather additional data to support a Phase 2a study in wet AMD. These studies are expected to generate data to inform the efficacy of UBX1325 in a wider range of patient populations, including those who are refractory to anti-VEGF treatment.

"We are very excited by the initial efficacy we see with UBX1325, including improvements in vision and structure in advanced patients, which suggest that UBX1325 may benefit a wide range of patients suffering from DME or wet AMD," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "UBX1325 targets an entirely novel mechanism to eliminate senescent cells in the retinal and choroidal vasculature, a potential root cause of disease progression, and could provide a valuable alternative or adjunctive treatment option to anti-VEGF therapies. We look forward to several important data readouts in the coming year that will further inform the optimal treatment regimen for UBX1325 in patients with DME and wet AMD."

"The imaging data demonstrating structural improvements in the retina are compelling at this stage of clinical development and represent defined endpoints for disease improvement," said Jeffrey Heier, M.D., Director of the Vitreoretinal Service and Retina Research at Ophthalmic Consultants of Boston. "Importantly, UBX1325 is an entirely new treatment modality for eye disease and is particularly exciting for this patient population for whom new therapeutic options could provide significant additional benefits alone or in combination with anti-VEGF agents."

The Phase 1, first-in-human, open-label, single-ascending dose study included 12 patients with advanced DME or wet AMD who were no longer expected to benefit from anti-VEGF therapies. UBX1325 was well tolerated in this patient population and demonstrated a favorable acute safety profile supporting further clinical development. There were no dose-limiting toxicities observed, with two nonserious, nondrug-related adverse events reported. In addition, patients treated with UBX1325 had improvements in vision and retinal structure as summarized below.

Treatment of patients with UBX1325 resulted in the following clinical changes as of June 30, 2021:

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

- Overall (across all doses): 10 of 12 patients showed a gain in ETDRS letters from baseline in BCVA at 2 weeks; 9 of 12 patients showed a gain at 4 weeks
- In high dose groups (5, 10 mcg): 6 of 6 patients showed a gain in ETDRS letters from baseline in BCVA at 2 weeks; 5 of 6 patients showed a gain at 4 weeks

Decrease in Central Subfield Thickness (CST)

- Overall (across all doses): 6 of 12 patients had a decrease (improvement) in CST at 2 weeks; 5 of 12 patients showed reductions at 4 weeks
- In high dose groups (5, 10 mcg): 4 of 6 patients showed decrease in CST at 2 weeks; 3 of 6 patients showed reductions at 4 weeks

Reduction in Subretinal / Intraretinal Fluid

- 3 of 4 patients with wet AMD had a reduction in subretinal / intraretinal fluid (SRF / IRF), and improvement in disease-relevant pathology

Jamie Dananberg, M.D., chief medical officer of UNITY, added, “The patients enrolled in this study had advanced disease for whom anti-VEGF therapies, the standard of care for DME and wet AMD, were no longer thought to be of benefit. Seeing treatment-related improvement in these difficult-to-treat patients is very promising and supports the investigation of UBX1325’s potential as a differentiated, disease-modifying treatment option for a broad patient population. We look forward to further exploring the efficacy of this novel mechanism to alter the course of disease progression in DME patients in the recently initiated Phase 2a study.”

Conference Call Information

UNITY will host a conference call and webcast for investors on Tuesday, July 6th at 8:00 a.m. ET to discuss the UBX1325 clinical data. 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 9423419. 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 March 31, 2021, filed with the Securities and Exchange Commission on May 11, 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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