UNITY Biotechnology Announces 48-Week Results from Phase 2 ENVISION Study of UBX1325 in Patients with Wet Age-Related Macular Degeneration

September 27, 2023 at 7:00 AM EDT

Patients on combination treatment with UBX1325 and aflibercept from weeks 24-48 maintained vision gains achieved at week 24 on aflibercept alone, with greater vision improvement in patients with more severe disease

Patients with prior anti-VEGF treatment and switched to UBX1325 monotherapy at study start maintained visual acuity through 24 weeks and had only a 1.5 letter decrease from baseline at week 48

40% of UBX1325-treated patients did not require anti-VEGF treatment through 48 weeks and 64% achieved an anti-VEGF treatment-free interval of over 24 weeks

UBX1325 was well tolerated in both monotherapy and combination arms

SOUTH SAN FRANCISCO, Calif., Sept. 27, 2023 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. (“UNITY”) [Nasdaq: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced results from Part B of the Phase 2 ENVISION study of UBX1325 in patients with wet age-related macular degeneration (AMD) who were not achieving optimum benefit with their ongoing anti-VEGF therapy.

UBX1325 demonstrated a favorable safety and tolerability profile in the combination and monotherapy arms with no cases of significant intraocular inflammation, retinal artery occlusion or endophthalmitis. Patients switched from every 8-week aflibercept to a combination of aflibercept and UBX1325 at week 24 maintained vision gains achieved with aflibercept alone through week 48. Patients in a pre-specified subgroup with poor visual acuity at baseline (≤60 ETDRS letters) gained 3.2 ETDRS letters on combination treatment between weeks 24 and 48.

In the UBX1325 monotherapy arm, patients maintained visual acuity for the duration of the study, with a mean change of +0.1 ETDRS letters at the 24-week time point and a mean change of -1.5 ETDRS letters at 48 weeks. 40% of UBX1325-treated patients did not need anti-VEGF rescue through 48 weeks and 64% of the patients achieved an anti-VEGF treatment-free period of over 24 weeks. The median time to first anti-VEGF rescue was 32 weeks.

“The ENVISION study shows that patients with wet AMD who switch from anti-VEGF to UBX1325 can maintain visual acuity with a significant reduction in anti-VEGF treatment burden. Patients with more severe disease may benefit from a combination of aflibercept and UBX1325,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “At this time, we are fully directing our resources towards the DME program, where we saw a statistically significant improvement in visual acuity with monotherapy UBX1325 treatment in the Phase 2 BEHOLD study.”

Additional 48-week data from the ENVISION study is expected to be presented at upcoming medical conferences. UNITY has initiated a Phase 2b study in patients with diabetic macular edema and expects to randomize the first patient in that study in Q4 2023.

About the ENVISION Study
The Phase 2 ENVISION study is a multi-center, randomized, double-masked, active-controlled study designed to evaluate the safety, tolerability, efficacy and durability of a repeat intravitreal injection of UBX1325 and aflibercept in patients with neovascular AMD evaluated through 48 weeks. The study enrolled 51 patients with an average baseline visual acuity of 60 ETDRS letters who had ongoing active disease with a baseline CST of approximately 370 µm and had been on anti-VEGF treatment for at least 6 months. All patients received a single run-in injection of aflibercept prior to the start of the study. Patients enrolled in the study were randomized into two arms: Patients in the UBX1325 monotherapy arm received an injection of UBX1325 at Week 0 and Week 4, and again at Week 24 and Week 28, for a total of four injections over the 48-week study. Patients in the control arm received an injection of aflibercept every 8 weeks through the duration of the full 48-week study. At Week 24 and Week 32, patients in the control arm received a combination of aflibercept with UBX1325, for a total of two doses of UBX1325 concurrent with their 8-week treatment interval. More information about the study is available here (NCT05275205).

About UBX1325
UBX1325 is an investigational compound being studied in retinal diseases including DME and wet AMD and 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. The Phase 2 BEHOLD study in patients with DME demonstrated that a single injection of UBX1325 resulted in a statistically significant and clinically meaningful improvement in mean Best Corrected Visual Acuity (BCVA) through 48 weeks compared to sham treatment. 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 retinal disease.

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, UNITY's 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 enrollment and results of the clinical trials in 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 the Company in general, see UNITY's most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the Securities and Exchange Commission on August 8, 2023, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission.

Media Contact
Evoke Canale
Katherine Smith
Katherine.Smith@evokegroup.com

Investor Contact
LifeSci Advisors, LLC
Joyce Allaire
jallaire@lifesciadvisors.com

UNITY
BIOTECHNOLOGY

Source: Unity Biotechnology, Inc.