UNITY Announces Design of Phase 2b ASPIRE Study Evaluating UBX1325 in Diabetic Macular Edema (DME)

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Phase 2b trial is a randomized, double-masked, active-controlled study designed to evaluate the safety and efficacy of UBX1325 (foselutoclax) compared to aflibercept over 24 weeks

First novel senolytic therapeutic candidate to be evaluated head-to-head against standard of care anti-VEGF in DME

SOUTH SAN FRANCISCO, Calif., June 21, 2023 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. ("UNITY") [Nasdaq: UBX], a biotechnology company developing therapeutics to slow, halt, or reverse diseases of aging, today announced the design of its Phase 2b ASPIRE clinical trial, which will evaluate UBX1325 (foselutoclax) head-to-head against aflibercept in previously treated patients with active diabetic macular edema (DME) who are not achieving optimal benefit from standard of care. UNITY expects to begin activating clinical trial sites in the third quarter and dose the first patient in the fourth quarter of 2023.

"The Phase 2b ASPIRE Study is designed to provide a clear and robust comparison between UBX1325 and the standard of care aflibercept in a head-to head trial in patients with DME," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "Participants in the study drug arm will receive three doses of UBX1325 over the duration of the study, in a frequency that mirrors the real-world dosing schedule in the aflibercept arm. Based on the significant improvement in vision and durable effect observed with UBX1325 in our Phase 2 BEHOLD study, we are excited to explore the potential benefit of UBX1325 as a monotherapy in patients with DME who are no longer benefiting from standard anti-VEGF therapy."

ASPIRE Trial Design

The Phase 2b ASPIRE study is a multi-center, randomized, double-masked, active-controlled study designed to evaluate the safety and efficacy of UBX1325 in comparison to aflibercept. Patients will be randomized 1:1 to receive either 10 µg UBX1325, or 2 mg of aflibercept control injections every eight weeks for six months.

- The study will enroll participants with non-proliferative diabetic retinopathy (NPDR) who have residual visual acuity deficits and excess fluid in the retina despite having received at least three anti-VEGF injections in the preceding six months.
- All participants will receive three doses of 2 mg aflibercept as a "run-in" prior to randomization.
- The study will enroll approximately 40 participants, with 20 participants per arm, who have plateaued in their anti-VEGF response and are no longer receiving optimal benefit from standard of care treatment.
- The primary efficacy endpoint will be mean change from baseline in Best Corrected Visual Acuity (BCVA) to week 24.
- Secondary endpoints will include change in BCVA over time, and CST change from baseline to week 24.

UNITY will begin activating clinical trial sites in the ASPIRE study in Q3 2023 and expects the first patient to be dosed in Q4 2023. With current timelines, last patient visit is expected to be in Q4 2024, with 16- and 24-week data readouts anticipated in Q1 2025.

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. 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 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, 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 the 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 risks negatively impacting the

development of preclinical and clinical drug candidates, 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, 2023, filed with the Securities and Exchange Commission on May 9, 2023, 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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Source: Unity Biotechnology, Inc.