UNITY Biotechnology Announces Extension of Phase 2b ASPIRE Clinical Study Evaluating UBX1325 in DME

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SOUTH SAN FRANCISCO, Calif., April 23, 2024 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. (“UNITY”) [NASDAQ: UBX], a biotechnology company developing therapeutics to slow, halt or reverse diseases of aging, today announced that the ongoing Phase 2b ASPIRE study of UBX1325 has been extended from 24 to 36 weeks to assess potentially greater durability compared to aflibercept. In addition, the study is being upsized from 40 to 50 patients to increase the statistical power. The ASPIRE study is designed to evaluate the safety, efficacy, and long-term durability of UBX1325 as a monotherapy compared head-to-head to aflibercept in patients with diabetic macular edema (DME).

“We previously demonstrated significant improvement in vision with extended durability in patients treated with UBX1325 in the BEHOLD proof-of-concept study and look forward to extending those findings in the current ASPIRE study,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “As the only treatment candidate in clinical development for DME that targets senescent cells, UBX1325 leverages a novel mechanism of action that could provide sustained improvements in visual acuity and lessen the treatment burden compared to current standard of care. We see UBX1325 as an emerging, potentially paradigm-shifting therapeutic approach in DME.”

As a result of extending the study, UNITY expects to disclose topline results from the ASPIRE study in two data readouts: 24-week primary endpoint data in the first quarter of 2025, and 36-week long-term extension data in the second quarter of 2025. The Company continues to believe that current cash, cash equivalents and marketable securities are sufficient to fund operations into the third quarter of 2025.

ASPIRE is a multi-center, randomized, double-masked, active-controlled study designed to evaluate the safety and efficacy of UBX1325 in comparison to aflibercept in previously treated patients with active DME who are not achieving optimal benefit from standard of care. The study is expected to enroll about 50 subjects who will be randomized 1:1 to receive either 10 µg UBX1325, or 2 mg of aflibercept control injections every eight weeks for six months after randomization. There will be no scheduled treatments in either arm between 24 and 36 weeks to allow direct comparison of durability of effect between the two treatment arms. The primary efficacy endpoint is non-inferiority to aflibercept as assessed by mean change from baseline in Best Corrected Visual Acuity (BCVA) to week 24. Secondary endpoints include change in BCVA from baseline over time, Central Subfield Thickness (CST) change from baseline over time, and proportion of participants who do not require anti-VEGF rescue, all through week 36. Additional information about ASPIRE (NCT06011798) can be found here.

About UBX1325
UBX1325 is an investigational compound being studied in retinal diseases, including DME, 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 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 X 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, the potential for UNITY to successfully commence and complete clinical studies of UBX1325 for DME 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 risks of delay or disruption of 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 Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission on April 15, 2024, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission.

Media Contact
Inizio Evoke Comms
Katherine Smith
Katherine.Smith@inizioevoke.com

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

Source: Unity Biotechnology, Inc.