UNITY Biotechnology Doses First Patients in Phase 2 ASPIRE Study of UBX1325 in DME

December 12, 2023 at 8:00 AM EST

Topline 16-week data expected in the fourth quarter of 2024

SOUTH SAN FRANCISCO, Calif., Dec. 12, 2023 (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 first patients have been dosed in the Phase 2 ASPIRE study of UBX1325 (foselutoclax), a Bcl-xL inhibitor being evaluated head-to-head against standard of care anti-VEGF in patients with diabetic macular edema (DME).

“Many patients with DME have poor vision despite frequent anti-VEGF injections and there is an urgent need to develop new treatment options for such patients,” said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. “There has been great interest from the physician community in the therapeutic potential of UBX1325, which is based on a novel senolytic mechanism of action, and we are excited to have dosed our first patients in the ASPIRE study. We look forward to sharing initial results from the study in the fourth quarter of 2024.”

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 diabetic macular edema (DME) who are not achieving optimal benefit from standard of care. It is expected to enroll about 40 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. 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 central subfield thickness (CST) change from baseline to week 24. Initial 16-week data is expected in the fourth quarter of 2024 and 24-week data expected in the first quarter of 2025. More information about ASPIRE (NCT06011798) can be found here.

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, 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 September 30, 2023, filed with the Securities and Exchange Commission on November 13, 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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