UNITY Biotechnology Provides Program Updates and Anticipated Milestones for 2022

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12-week safety and efficacy analysis from a Phase 2 study of UBX1325 in diabetic macular edema (DME) expected in first half 2022 and wet age-related macular degeneration (wet AMD) expected in the second half of 2022

Phase 2 study of UBX1325 in wet AMD to include comparison with aflibercept

Additional pipeline programs targeting age-related diseases continue to advance

SOUTH SAN FRANCISCO, Calif., Jan. 04, 2022 (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 for its Phase 2 study of UBX1325 in wet age-related macular degeneration (AMD) and anticipated milestones for 2022.

"2021 was a transformational year for us as our senolytic candidate UBX1325 represents a novel and impressive new class of retinal medicine for the treatment of diabetic macular edema and age-related macular degeneration, as evidenced by Phase 1 results as well as preclinical research published in the journal *Cell Metabolism*," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "Bcl-xL inhibition – a mechanism for selectively eliminating senescent cells in diseased retinal tissue – has emerged as a promising alternative to anti-VEGF therapy with potentially improved outcomes and dosing regimens that lessen the treatment burden for patients. Looking ahead to 2022, we are working with leading retinal specialists in the field to advance UBX1325 in Phase 2 clinical studies, as well as advancing our senescence-related programs across our pipeline."

UNITY expects to share 12-week safety and efficacy data from its ongoing Ph2 study of UBX1325 in DME in the first half of 2022, and to share initial data from the Ph2 study in wet AMD in the second half of 2022.

UBX1325 Program:

The protocol for the Phase 2 proof of concept study of UBX1325 in wet AMD has been submitted to the U.S. FDA and we anticipate initiating that study in the first half of 2022. The Phase 2 clinical trial is a multi-center, randomized, double-masked study designed to evaluate the safety, efficacy and durability of UBX1325. The study design includes a control arm using standard-of-care aflibercept in patients with neovascular AMD. Patients will be randomized to receive either two doses of UBX1325 10 mcg at week 0 and week 4, or aflibercept 2 mg every eight weeks. Safety and efficacy will be assessed at 8, 16 and 24 weeks. The primary endpoint is improvement in visual acuity, as measured by change in BCVA from baseline.

The study is expected to enroll 46 patients with wet AMD who have had at least three intravitreal injections of anti-VEGF therapy in the preceding six months and who have residual sub- or intra-retinal fluid. Patients will have received their last anti-VEGF treatment approximately 4-8 weeks prior to screening, and all patients will be followed for approximately 24 weeks after dosing with either UBX1325 or aflibercept.

"The dosing regimen in this Phase 2 study is based on the response kinetics in the Phase 1 study as well feedback from a team of leading clinicians and scientists who advised on the study design," said Jamie Dananberg, M.D., chief medical officer of UNITY. "In wet AMD, the choroidal vasculature is impacted, and we believe that a repeat dose of UBX1325 may result in optimum efficacy and durability for patients."

Additional Pipeline Programs:

UNITY continues to investigate new modalities around senescence-related mechanisms and other biology implicated as drivers of diseases of aging:

Tie2-VEGF bispecific program:

Tie2 is a receptor tyrosine kinase that is implicated in regulating barrier function in blood vessels of the eye, which are affected in several prevalent eye diseases. Tie2 is an important key regulator of the vascular endothelium in the eye and dysregulation of this pathway leads to loss of barrier integrity and healthy vasculature. Preliminary studies suggest that cellular senescence in aging eyes may induce Ang-2 and therefore deactivate Tie2, leading ocular edema.

The Tie2-VEGF bispecific has dual functionality on two validated targets for retinal diseases. In addition to direct activation of Tie2, the bispecific candidate is designed to neutralize VEGF-A and VEGF-B. UNITY anticipates that a Tie2 x VEGF bispecific clinical candidate will be selected and enter IND-enabling studies in 2022. We believe that direct agonism of Tie2 may be superior to antagonism of Ang2 which relies on adequate levels of endogenous Ang1 to activate the Tie2 pathway.

UBX2050 Tie2 antibody program:

The investigational Tie2 antibody (UBX2050) may be an orthogonal approach to restoring barrier function and vascular function. UNITY is exploring a number of indications for UBX2050 and expects to nominate a Development Candidate in 2022.

UBX2089 α-Klotho program:

UNITY has licensed its α-Klotho (UBX2089) program to Jocasta Neuroscience for development and commercialization in cognitive dysfunction

associated with neurological and psychiatric conditions. The α-Klotho protein has been implicated in human cognition and may provide benefits in age-related cognitive diseases, including Alzheimer's Disease. The licensing agreement included an upfront payment and provides for development and approval milestones, as well as sales-based royalties per indication.

UBX2089 is expected to enter IND-enabling studies in 2022.

Discovery programs:

UNITY continues to advance preclinical programs targeting new mechanisms of action for the treatment of age-related diseases, including both senolytic and non-senolytic mechanisms.

Anticipated 2022 Milestones

- 1H 2022 – UBX1325 complete safety and efficacy data through 24 weeks from the additional wet AMD cohort of the Phase 1 study (UBX1325-01 Study)
- 1H 2022 – UBX1325 12-week safety and efficacy data from the Phase 2a DME study (UBX1325-02 Study)
- 2H 2022 – UBX1325 24-week safety and efficacy data from the Phase 2a DME study (UBX1325-02 Study)
- 2H 2022 – UBX1325 16-week safety and efficacy data from the Phase 2 wet AMD study (UBX1325-03 Study)
- 2022 – Tie2 antibody (UBX2050), Tie2/VEGF bispecific and α-Klotho (UBX2089) projected to enter IND-enabling studies

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. 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. UBX1325 has shown a favorable safety profile and improvements in visual acuity sustained through 24 weeks following a single dose in a Phase 1 clinical study in advanced vascular eye disease. 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, 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 September 30, 2021, filed with the Securities and Exchange Commission on November 10, 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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