UNITY Biotechnology Announces 12-week data from UBX0101 Phase 2 Clinical Study in Patients with Painful Osteoarthritis of the Knee

August 17, 2020

- **UBX0101 failed to meet 12-week primary endpoint**
- **Guidance for UNITY's Bcl-xL inhibitor UBX1325 in retinal disease remains unchanged**
- **UNITY to focus senescence programs on ophthalmologic and neurologic diseases in near-term**
- **UNITY to hold investor and analyst conference call today, Monday, August 17, 2020, at 8:00 a.m. EDT**

SOUTH SAN FRANCISCO, Calif., Aug. 17, 2020 (GLOBE NEWSWIRE) -- UNITY Biotechnology, Inc. ("UNITY") [NASDAQ:UBX], a biotechnology company developing therapeutics to extend healthspan by slowing, halting or reversing diseases of aging, today announced the 12-week results from the Phase 2 study of UBX0101, a p53/MDM2 interaction inhibitor, in patients with moderate-to-severe painful osteoarthritis (OA) of the knee. There was no statistically significant difference between any arm of UBX0101 and placebo at the 12-week endpoint for change from baseline in WOMAC-A, an established measurement of pain in OA. Given these results, UNITY does not anticipate progressing UBX0101 into pivotal studies and will narrow the company's near-term focus to its ongoing ophthalmologic and neurologic disease programs.

"Osteoarthritis of the knee is a debilitating disease for many individuals," said Jamie Dananberg, M.D., chief medical officer of UNITY. "While we are disappointed in the outcome of the 12-week results of the Phase 2 study of UBX0101, I would like to acknowledge our team's hard work and commitment to executing a robust study that has provided clear results."

The company expects to complete collection of the Phase 2 24-week data, as well as that from the ongoing Phase 1b high-dose, repeat-dose study in the second half of 2020. The full results from the Phase 2 and Phase 1b studies will be presented at a future medical meeting.

Phase 2 12-week Data

In the Phase 2 double-blind, placebo-controlled study, 183 patients with moderate to severe painful OA of the knee were randomized to receive placebo, 0.5 mg, 2.0 mg or 4.0 mg of UBX0101 via a single intra-articular injection. The analysis results for the primary endpoint are shown in the table below.

	Primary Endpoint: Least Square Means Change from Baseline in WOMAC-A (0-4 scale) at Week 12		
Treatment	**WK 12 CFBL**	**Pbo-Adjusted CFBL Wk 12**	**P-Value***
Placebo (N = 46)	-1.017	N/A	N/A
UBX0101 0.5 mg (N = 45)	-0.924	0.093	0.5222
UBX0101 2.0 mg (N = 46)	-1.052	-0.035	0.8069
UBX0101 4.0 mg (N = 46)	-1.019	-0.002	0.9870

* P-Value is obtained from MMRM testing CFBL against Placebo

UBX0101 was well-tolerated at all dose levels and adverse events (AEs) were consistent with previously reported data. There were no treatment-related serious AEs and only one patient discontinued because of an AE (for an unrelated cardiovascular event). The most common treatment emergent AE was procedural pain in the study knee (n = 10/183 (5.5%)).

"Developing novel treatments that selectively eliminate or modulate senescent cells is at the heart of what we do, and we have generated valuable data that will enable us to learn from this study and inform future studies in diseases of aging," said Anirvan Ghosh, Ph.D., chief executive officer of UNITY. "While these are not the results we had hoped for, the evidence that senescent cells contribute to diseases of aging remains compelling, and we are excited to advance UBX1325 for retinal diseases, which inhibits Bcl-xL, a distinct senolytic target. Diabetic macular edema and diabetic retinopathy are attractive not only because of the strength of underlying biology, but also because of the sensitive, quantitative, and objective clinical assessments available. The burden of senescent cells in various diseases of aging is increasingly evident, which together with our research gives us great conviction in our science and the future of our pipeline."

Additional information about the study can be found on www.clinicaltrials.gov (NCT04129944).

Financial Outlook

Based on current operating plans, UNITY believes that current cash, cash equivalents and investments are sufficient to fund operations well into 2022.

Conference Call Information
UNITY will host a conference call and webcast for investors on Monday, August 17, 2020 at 8:00 a.m. EDT to discuss the UBX0101 clinical data. The live webcast can be accessed in the "Investors and Media" section of our website, www.unitybiotechnology.com, under "Events & Presentations" or by clicking here. You may also listen to the call by dialing 1-877-235-8637 within the U.S. or 1-704-815-6400 outside the U.S. and providing conference ID

6688134. A replay will be available two hours after the completion of the call and can be accessed in the “Investors & Media” section of our website, www.unitybiotechnology.com, under “Events and Presentations.”

About UNITY

UNITY is developing a new class of therapeutics to slow, halt or reverse diseases of aging. UNITY's initial focus is on creating medicines to selectively eliminate or modulate senescent cells and thereby provide transformative benefit in age-related diseases, such as osteoarthritis, eye diseases, neurological diseases and pulmonary diseases. More information is available at www.unitybiotechnology.com or follow us on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements including statements related to the expected timing of date from the 24-week endpoints from UNITY’s Phase 2 clinical study and Phase 1b high-dose, repeat-dose clinical study of UBX0101, statements regarding UNITY’s understanding of cellular senescence and the role it plays in osteoarthritis and retinal diseases, the potential for UNITY to develop therapeutics to extend healthspan, including UBX1325 for retinal disease, expectations regarding the results of UNITY’s clinical studies 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. 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, 2020, filed with the Securities and Exchange Commission on July 31, 2020, 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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