# UNITY Biotechnology, Inc. Announces First Patient Dosed in Phase 2 Study of UBX0101 in Osteoarthritis of the Knee

October 31, 2019

SAN FRANCISCO, Oct. 31, 2019 (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 patient has been dosed in a Phase 2 study of UBX0101 in patients with osteoarthritis (OA) of the knee.

“In June, we announced promising results from our Phase 1 study of UBX0101 in patients with OA of the knee showing that our senolytic molecule was well tolerated and had a dose-dependent improvement in pain and function across multiple clinical endpoints,” said Jamie Dananberg, chief medical officer of UNITY. “By selectively targeting the senescent cells that accumulate in osteoarthritic knee tissue, we aim to treat an underlying cause of the disease, which is an entirely new approach compared to current standards of care that only temporarily address symptoms of OA. Ultimately, our aim is to change the course of this debilitating disease.”

The Phase 2 study of UBX0101 in patients with painful, moderate-to-severe OA of the knee is expected to enroll approximately 180 patients. Initial 12-week results are expected in the second half of 2020. The study is a randomized, double-blind, placebo-controlled study evaluating three UBX0101 doses (0.5mg, 2.0mg and 4.0mg) administered via a single intra-articular injection. The primary measure will be an assessment of knee pain at 12 weeks using the WOMAC®-A instrument. Secondary measures will include safety and tolerability, pain (by a 0-10 Numerical Rating Scale, or NRS) and function (by WOMAC®-C) at 12 weeks, as well as all of these endpoints at 24 weeks.

**About UBX0101**

UBX0101 is being evaluated for the treatment of musculoskeletal disease, with an initial focus on OA of the knee. UBX0101 is a senolytic small molecule inhibitor of the MDM2/53 protein interaction. Disruption of this protein interaction can trigger the elimination of senescent cells. Initial results from a Phase 1 clinical trial in patients with moderate-to-severe OA of the knee were announced in June 2019. The study demonstrated that UBX0101 was well-tolerated. Dose-dependent improvement in several clinical measures, including pain and function, as well as modulation of multiple senescence-associated secretory phenotype (SASP) factors and disease-related biomarkers, was observed after a single dose of UBX0101.

**About Osteoarthritis**

OA is a degenerative disease that negatively impacts cartilage, subchondral bone and the synovial tissue lining the joint, causing pain and physical impairment. OA is a highly prevalent disease, symptomatically affecting as many as 10% to 15% of the world’s population over age 60, and results in a decline in quality of life. The most common joint affected by OA is the knee. Importantly, the current standard of care addresses only the symptoms of OA, which temporarily reduces joint inflammation and pain, but does not address the root cause of disease. UNITY believes that the accumulation of senescent cells is a significant contributing factor in OA and that the selective elimination of these cells may be therapeutic.

**About UNITY**

UNITY is developing therapeutics to extend healthspan by slowing, halting or reversing diseases of aging. UNITY's initial focus is on creating senolytic medicines to selectively eliminate senescent cells and thereby treat age-related diseases, such as osteoarthritis, eye 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 UNITY’s understanding of cellular senescence and the role cellular senescence plays in diseases of aging,; UBX101’s potential to selectively eliminate senescent cells in patients with OA of the knee; the potential benefits, activity, effectiveness and safety of UBX0101; the design of UNITY’s Phase 2 study and expected timing of the expected timing of the availability and announcement of initial results from the Phase 2 study. 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. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the uncertainties inherent in the drug development process, including UNITYs early stage development and its understanding of cellular senescence biology; the expectation that UNITY will need additional funds to finance its operations; UNITY’s ability to initiate and/or complete clinical trials; the unpredictability of the regulatory process; the possibility that UNITY’s clinical trials will not be successful; UNITY’s dependence on the success of UBX0101; UNITY’s reliance on third parties for the manufacture of UNITY’s product candidates; possible regulatory developments in the United States and foreign countries; and UNITY’s ability to attract and retain senior management personnel. 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 recently filed Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the Securities and Exchange

Commission on August 7, 2019, as well as other documents that may be filed by UNITY from time to time with the Securities and Exchange Commission. This press release concerns drug candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. They are currently limited by Federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

Investors

Endurance Advisors
Peter Rahmer
prahmer@enduranceadvisors.com

Media

Canale Communications
Jason Spark
jason@canalecomm.com

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