UNITY Biotechnology, Inc. Announces Plan for Phase 2 Clinical Study of UBX0101 in Osteoarthritis of the Knee

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SAN FRANCISCO, July 30, 2019 (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 details for the planned 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 had a dose-dependent response across multiple clinical endpoints," said Keith Leonard, chairman and chief executive officer of UNITY. “We look forward to substantiating the promising results we observed in Phase 1 in a larger Phase 2 study. We will also be gathering additional information on duration of effect out to 24 weeks, validating early safety and dose-finding, and characterizing potential disease-modifying effects on bone and cartilage.”

UBX0101 Clinical Development Update

In June 2019, UNITY announced results from its first-in-human Phase 1 study of UBX0101 (NCT03513016) in patients with moderate-to-severe OA of the knee. In this study, UBX0101 was well-tolerated. Improvement in several clinical outcomes, including pain and function, as well as modulation of certain senescence-associated secretory phenotype (SASP) factors and disease-related biomarkers was observed after a single dose of UBX0101.

UNITY plans to initiate a Phase 2 study of UBX0101 in patients with painful, moderate-to-severe OA of the knee. The study is expected to enroll approximately 180 patients with initiation expected in the fourth quarter of 2019 and initial 12-week results expected in the second half of 2020. This will be a randomized, double-blind, placebo-controlled study evaluating three doses (0.5mg, 2mg and 4mg) of UBX0101 administered via a single intra-articular injection. The primary measure will be an assessment of pain at 12 weeks using the WOMAC-A instrument. Secondary measures will include safety and tolerability, pain (by 10 point Numerical Rating Scale, or NRS) and function (by WOMAC-C) at 12 weeks, as well as similar measures at 24 weeks.

In addition, UNITY plans to study the safety, tolerability and initial effectiveness of both a new higher dose and repeat doses in a parallel Phase 1B study. Details of that study will be forthcoming.

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/p53 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. Improvement in several clinical measures, including pain and function, as well as modulation of certain 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 surrounding 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, followed by the hip, wrist, ankle, and shoulder. 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 our expectations of the sufficiency of our cash; statements related to our understanding of cellular senescence and the role cellular senescence plays in diseases of aging; our potential to selectively eliminate senescent cells in patients with OA of the knee; the potential benefits, activity, effectiveness and safety of UBX101; the design of our planned Phase 2 OA trial; and timing of initiation of our Phase 2 OA trial and the data read out. 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. 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 recently filed Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, filed with the Securities and Exchange Commission on May 8, 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 a drug candidate that is under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration. It is currently limited by Federal law to investigational use, and no representation is made as to its safety or effectiveness for the purposes for which it is being investigated.

Investors
Endurance AdvisorsPeter Rahmerprahmer@enduranceadvisors.com

Media
Canale CommunicationsJason Sparkjason@canalecomm.com

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