# UNITY Biotechnology Expands Ongoing UBX0101 Phase 1 Study to Further Evaluate SASP Factors in Osteoarthritis of the Knee

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*- Results expected in the second quarter of 2019 -*

SAN FRANCISCO, Jan. 22, 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 further expansion of the Phase 1 study of UBX0101 in patients with moderate to severe osteoarthritis (OA) of the knee with a cohort of an additional 24 patients at the highest evaluated dose (4mg) (Part B). Part B is intended to supplement the initial Phase 1 trial (Part A) by further evaluating the impact of UBX0101 on specific pro-inflammatory and extracellular matrix modifying factors within the Senescence-Associated Secretory Phenotype (SASP).

To measure SASP factors, an adequate volume of synovial fluid is required in the knee joint capsule to collect a sample. In Part A of the Phase 1 study, UNITY sought to collect synovial fluid via simple aspiration; however, a number of patients had an insufficient amount of fluid for sampling. Part B will provide an increased sample size for SASP assessment by allowing saline lavage in patients who do not have adequate fluid to collect via simple aspiration. The lavage procedure was not conducted in Part A to avoid potential confounding effects the procedure may have had on the assessment of safety and tolerability of UBX0101. This lavage procedure was used successfully as a part of the previously conducted biomarker study to explore the relationship between senescence burden, SASP factors in synovial fluid, synovial inflammation and OA disease severity.

“By expanding the Phase 1 study, we will enhance our understanding of the relationship between treatment with UBX0101 and any change in SASP factors to help guide further clinical development,” said Jamie Dananberg, M.D., chief medical officer at UNITY. “We are encouraged by the safety and tolerability observed to date in this first study of a senolytic drug in patients with OA. It is that experience in patients that gives us the confidence to initiate Part B at the highest evaluated dose.”

The addition of Part B follows review of aggregate blinded safety, tolerability and drug exposure data from Part A, which has completed enrollment and a minimum of 2-week assessments of all patients. These data support expanding into a Part B cohort at the highest evaluated dose (4 mg). UNITY remains blinded to clinical outcomes from Part A. Top-line results from both Part A and Part B are expected in the second quarter of 2019.

**About the UBX0101 Phase 1 Clinical Study**
The Phase 1 clinical trial of UBX0101 is a randomized, double-blind, placebo-controlled, single ascending dose study evaluating the safety, tolerability and pharmacokinetics of a single intra-articular injection of UBX0101 in patients diagnosed with moderate to severe OA of the knee.

In Part A, 48 patients were randomly assigned to receive UBX0101 or placebo in 3:1 randomization by dose level cohort. Primary endpoints are safety and tolerability. Secondary and exploratory endpoints include plasma pharmacokinetics, synovitis as measured by MRI, pain and SASP factors in synovial fluid and plasma.

In Part B, approximately 24 patients will be randomized to receive UBX0101 (4 mg dose) or placebo in a 2:1 randomization. Primary endpoints are safety and tolerability. Secondary endpoints include SASP factors in synovial fluid and plasma, pain, and drug exposure. Synovial fluid samples will be obtained pre-treatment and at four weeks. Key endpoints will be assessed at four weeks and patients will be followed for a total of six weeks following treatment administration.

Additional information about the study can be found on www.clinicaltrials.gov (NCT03513016).

**About Cellular Senescence and Senolytic Medicines**
Cellular senescence is a natural biological state in which a cell permanently halts division. Senescent cells accumulate with age and secrete as many as 100 different biologically active proteins, including pro-inflammatory factors, proteases, pro-fibrotic factors and growth factors that disturb the tissue microenvironment. This collection of secreted proteins is referred to as the SASP. In addition to its effects on tissue function, the SASP contains factors that induce senescence in neighboring cells, setting off a cascade of events that culminates in the formation of the functionally aged and/or diseased tissue that appears to underlie a variety of age-related diseases. UNITY believes that the elimination of senescent cells will remove SASP factors —addressing a root cause of diseases of aging. Senolytic medicines, or treatments designed to selectively remove senescent cells, target the SASP at its source, and may have a more durable impact on certain diseases of aging than current therapies.

**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 but not limited to statements related to the role of cellular senescence in diseases of aging, UNITY’s potential to selectively eliminate senescent cells and thereby treat patients with OA, the rationale for adding a Part B cohort to the ongoing Phase 1 OA trial and expanding the number of patients receiving the highest evaluated dose, and the timing of the data read out and nature of endpoints we expect to achieve in the Phase 1 OA trial. Such forward-looking statements involve substantial risks and uncertainties that could cause

UNITY's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including UNITY's early stage of development and its understanding of senescence biology, the clinical trial process, UNITY's ability to demonstrate sufficient evidence of efficacy and safety in its clinical trials and pre-clinical studies, and the results of preclinical studies may not be predictive of future results. UNITY undertakes no obligation to update or revise any forward-looking statements. 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 September 30, 2018, filed with the Securities and Exchange Commission on November 7, 2018, 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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