UNITY Biotechnology Announces Additional Cohort to Evaluate Higher Dose in Ongoing UBX0101 Phase 1 Study in Osteoarthritis of the Knee

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Initial study results expected to be available in second quarter of 2019

SAN FRANCISCO, Dec. 03, 2018 (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 that it will include an additional cohort of patients in the Phase 1 single ascending dose clinical study of UBX0101 in patients with moderate to severe osteoarthritis (OA) of the knee. Additional patients will be enrolled in the study in order to evaluate a higher dose of UBX0101 administered in a single intra-articular injection.

UNITY has completed enrollment in Cohorts 1 through 5 (0.1 to 2 mg dose). The amendment follows an interim review of aggregate blinded safety and tolerability, and drug exposure data from these cohorts. The data observed to date support the exploration of a higher dose (4 mg) of UBX0101 in an additional cohort (Cohort 6). Results from Cohorts 1 through 5 were originally expected to be available in the first quarter of 2019. With the addition of Cohort 6, initial results from the study are now expected to be available in the second quarter of 2019.

“We believe that understanding a broader dose range of UBX0101 will be important in establishing the appropriate doses for potential future clinical development,” said Jamie Dananberg, M.D., chief medical officer at UNITY. “We look forward to sharing results from the study in the second quarter of 2019.”

About the 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. Patients are randomly assigned to receive UBX0101 or placebo in 3:1 randomization by dose level cohort. Primary endpoints for the study are safety and tolerability. Secondary and exploratory endpoints include plasma pharmacokinetics, synovitis as measured by MRI, pain and synovial fluid Senescence-Associated Secretory Phenotype (SASP) factors. Additional information about the study can be found on www.clinicaltrials.gov.

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, our potential to selectively eliminate senescent cells and thereby treat patients with osteoarthritis, the benefits we expect from adding a sixth cohort to the ongoing Phase 1 OA trial and increasing the dosage level of UBX0101, and the timing of the data read out and nature of the endpoints we expect to achieve in this 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 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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