UNITY Biotechnology Completes Enrollment in Phase 1b Study of UBX0101

March 31, 2020

– Topline 12- and 24-week results expected in 2H 2020 –

SAN FRANCISCO, March 31, 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 updates related to UBX0101.

In February 2020, UNITY announced that it had dosed the first patients with moderate-to-severe osteoarthritis (OA) of the knee in a Phase 1b study to explore the safety, tolerability and initial efficacy of a single 8.0 mg dose or multiple doses (two 4.0 mg doses separated by one month) of UBX0101, an inhibitor of the p53/MDM2 protein-protein interaction. The study has now completed enrollment of 35 patients. Both 12- and 24-week data are currently expected in the second half of 2020.

Also in February 2020, UNITY announced completion of enrollment of a Phase 2 study of UBX0101 in patients with moderate-to-severe OA of the knee. This study, now fully enrolled with 183 patients, is randomized, double-blind, and placebo-controlled and will evaluate safety and efficacy of three doses of UBX0101 (0.5, 2.0 and 4.0 mg) administered via a single intra-articular injection. UNITY is focused on patient safety and has reviewed clinical protocol and operations in light of recent events and guidance from the Food and Drug Administration. The study currently remains on-track to report 12- and 24-week results in the second half of 2020.

“I am proud of our clinical team and investigators across the UBX0101 program as we continue to make great progress towards key data read-outs in the second half of the year,” said Jamie Dananberg, M.D. and chief medical officer of UNITY. “The COVID-19 pandemic has created extraordinary challenges for many clinical studies and we have been proactive in working with our investigators and sites to adapt to these challenges while consistently maintaining patient safety as a top priority.”

About UBX0101
UBX0101 is being evaluated for the treatment of musculoskeletal disease, with an initial focus on osteoarthritis (OA) of the knee. UBX0101 is a small molecule inhibitor of the p53/MDM2 protein-protein interaction. UBX0101 binds to MDM2, raising p53 levels which, in turn, we believe, causes 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, were observed after a single dose of UBX0101.

About Osteoarthritis
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.

About UNITY
UNITY is developing therapeutics to extend healthspan with an initial focus on cellular senescence. UNITY believes that the accumulation of senescent cells is a fundamental mechanism of aging and a driver of many common age-related diseases. Cellular senescence is a natural biological state in which a cell permanently halts division. As senescent cells accumulate with age, they begin secreting inflammatory factors, proteases, fibrotic factors, and growth factors, that disturb the tissue micro-environment. This collection of secreted proteins is referred to as the Senescence Associated Secretory Phenotype, or SASP. UNITY is developing senolytic medicines to eliminate senescent cells and thereby stop the production of the SASP, which UNITY believes addresses a root cause of age-related diseases. By stopping the production of the SASP at it source, UNITY believes senolytic medicines could slow, halt, or reverse diseases such as osteoarthritis and age-related eye 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 age-related diseases; the potential for UNITY to develop medicines that eliminate senescent cells; the potential benefits, activity, effectiveness and safety of UBX0101 in patients with OA of the knee; the design of and timing of data read out from UNITY’s Phase 2 OA study; and the design of and timing of data read out from UNITY’s Phase 1b OA 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. 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 Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on March 11, 2020, 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.

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Source: Unity Biotechnology, Inc.