



## UNITY Biotechnology Provides Pipeline and Business Updates

February 25, 2020

*– Phase 2 study of UBX0101 in patients with osteoarthritis has completed enrollment –*

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

*– First patient dosed in phase 1b study to explore higher dose and repeat doses –*

*– First-in-human study initiation for ophthalmology program expected in 2H 2020 –*

SAN FRANCISCO, Feb. 25, 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 provided pipeline and business updates.

### Recent Highlights and Business Updates

#### **Osteoarthritis – UBX0101**

In October 2019 UNITY announced that the first patient had been dosed in a Phase 2 study of UBX0101, an inhibitor of the MDM2/p53 protein-protein interaction, in patients with moderate-to-severe osteoarthritis (OA) of the knee. The study is now fully enrolled with 183 patients. The study is randomized, double-blind, and placebo-controlled and will evaluate three doses (0.5 mg, 2.0 mg and 4.0 mg) of UBX0101 administered via a single intra-articular injection. Both 12- and 24-week results are now expected in the second half of 2020.

"We are pleased to announce the completion of enrollment ahead of schedule in our Phase 2 study of UBX0101 in patients with moderate-to-severe osteoarthritis of the knee," said Keith Leonard, chairman and chief executive officer of UNITY. "We believe the rapid enrollment of this study can, in part, be explained by the significant unmet need of patients suffering from this debilitating condition. We now anticipate that both the 12-week and 24-week data will be available in the second half of this year."

UNITY has also dosed the first patients in a Phase 1b study to explore the safety, tolerability and initial efficacy of a higher dose (8.0 mg) and repeated doses (4.0 mg x 2, separated by 1 month) of UBX0101. The study is expected to enroll approximately 36 patients with 12-week results expected in the second half of 2020.

#### **Ophthalmology**

UNITY's lead ophthalmology candidates, UBX1325 and UBX1967, are currently in the final phases of Investigational New Drug (IND) enabling non-clinical toxicology studies. Both senolytic molecules are inhibitors of particular members of the Bcl-2 family of apoptosis regulatory proteins which have shown distinct pharmacokinetic profiles in preclinical studies. UNITY intends to complete IND-enabling studies for both molecules prior to selecting the first molecule to advance to a first-in-human study to explore safety and tolerability of this novel mechanism of action for age-related eye diseases. UNITY expects to initiate a Phase 1 safety study for this program in the second half of 2020. The overall clinical program is directed at multiple age-related diseases of the eye, such as age-related macular degeneration, diabetic retinopathy and diabetic macular edema.

#### **Cash Update**

As of December 31, 2019 cash, cash equivalents and investments were \$125.0 million (unaudited). UNITY expects this is sufficient to fund operations into the second half of 2021.

UNITY expects to release its audited financial results for 2019 on March 11, 2020.

#### **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 MDM2/p53 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, 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.

#### **About Ophthalmology (Age-Related Eye Diseases)**

The majority of significant eye diseases are age-related, with the prevalence of vision-threatening disease increasing significantly over the age of 75. Of the 285 million individuals worldwide living with visual impairment, 65% are over the age of 50. The individual diseases that are associated with these figures include age-related macular degeneration, diabetic eye diseases and glaucoma, all of which have a high prevalence and significant

unmet need in either prevention or therapeutic options.

#### **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 its 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](http://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, pace of enrollment in, and timing of data read out from UNITY's Phase 2 OA study; the design of and timing of data read out from UNITY's Phase 1b OA study; the mechanism of action and pharmacokinetic profiles of UBX1325 and UBX1967; UNITY's ability to successfully complete ongoing pre-clinical studies of UBX1325 and UBX1967; the timing of initiation of the first Phase 1 study of UBX1325 or UBX1967 in age-related eye diseases; the potential scope of UNITY's overall clinical program in age-related eye diseases; and UNITY's expectations with regard to the sufficiency of its cash runway. 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 September 30, 2019, filed with the Securities and Exchange Commission on November 6, 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.

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