BioTime Announces Issuance of U.S. Patent for Method of Reducing Cavitation in Patients with Acute Spinal Cord Injury

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ALAMEDA, Calif.--(BUSINESS WIRE)--May 6, 2019-- BioTime, Inc. (NYSE American and TASE: BTX), a clinical-stage biotechnology company developing cellular therapies for unmet needs, announced today the issuance of a Notice of Allowance for a patent from the United States Patent and Trademark Office (USPTO) for United States Patent Application No. 15/156,316 for a method of reducing spinal cord injury (SCI)-induced parenchymal cavitation in patients that have suffered an acute spinal cord injury. The claimed method involves injecting oligodendrocyte progenitor cells (OPCs) derived from human pluripotent stem cells into the SCI site and covers both human embryonic and induced pluripotent stem cell-derived OPCs. The issued patent would have a term that expires no earlier than 2036.

“We believe OPC1 acts via several distinct mechanisms to aid the recovery of SCI patients, one of which is the prevention or reduction of cavitation, and we are pleased at having received an allowance on this important patent, which we believe further enhances our OPC1 cell therapy program,” stated Brian M. Culley, Chief Executive Officer of BioTime. “Cavitation is a destructive process that occurs within the spinal cord following injuries and typically leads to permanent loss of motor and sensory function. Patients with cavitation may develop a condition known as syringomyelia, which results in additional neurological and functional damage and can result in chronic pain. A key finding from our Phase I/IIa SCiStar clinical study of OPC1 for treating acute SCIs was that 95% of subjects showed evidence that OPC1 cells engrafted at the injury site and helped to prevent cavitation, which was confirmed via magnetic resonance imaging (MRI) scans.”

About OPC1

OPC1 is currently being tested in Phase I/IIa clinical trial known as SCiStar, for the treatment of acute spinal cord injuries. OPCs are naturally-occurring precursors to the cells which provide electrical insulation for nerve axons in the form of a myelin sheath. SCI occurs when the spinal cord is subjected to a severe crush or contusion injury and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and loss of bladder control and other body functions. The clinical development of the OPC1 program has been partially funded by a $14.3 million grant from the California Institute for Regenerative Medicine. OPC1 has received Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of acute SCI and has been granted Orphan Drug designation from the U.S. Food and Drug Administration (FDA).

About the SCiStar Trial

The SCiStar trial is an open-label, single-arm trial testing three sequential escalating doses of OPC1 administered at up to 20 million OPC1 cells in 25 subjects with subacute motor complete (AIS-A or AIS-B) cervical (C-4 to C-7) SCI. These individuals have essentially lost all movement below their injury site and experience severe paralysis of the upper and lower limbs. AIS-A subjects have lost all motor and sensory function below their injury site, while AIS-B subjects have lost all motor function but may have retained some minimal sensory function below their injury site. OPC1 is administered 21 to 42 days post-injury. Subjects will be followed by neurological exams and imaging procedures to assess the safety and activity of the product.

Improvements in upper extremity motor function are being measured using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) scale, widely used to quantify functional status of patients with spinal cord injuries. Both subjects and physicians consistently report that improvements in upper extremity motor function are the most desirable functional improvement target in the quadriplegic population, since even relatively modest changes can potentially have a significant impact on functional independence, quality of life and cost of care. The SCiStar study is monitoring two separate ISNCSCI measurements of upper extremity motor function. The upper extremity motor score (UEMS), is a linear scale used to quantify motor function at each of five upper extremity muscle groups driving arm and hand function; these scores are also used to determine "motor levels", which define the level within the cord above which a subject has normal function. As suggested by existing research, patients with severe spinal cord injuries that show two motor levels of improvement on at least one side may regain the ability to perform daily activities such as feeding, dressing and bathing, which significantly reduces the overall level of daily assistance needed for the patient and associated healthcare costs.

About BioTime, Inc.

BioTime is a clinical-stage biotechnology company developing new cellular therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. BioTime’s programs are based on its proprietary cell-based therapy platform and associated development and manufacturing capabilities. With this platform BioTime develops and manufactures specialized, terminally-differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed either to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or administered as a means of helping the body mount an effective immune response to cancer. BioTime’s clinical assets include (i) OpRegen ®, a retinal pigment epithelium transplant therapy in Phase I/IIa development for the treatment of dry age-related macular degeneration, the leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase I/IIa development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. For more information, please visit www.biotimeinc.com.

Forward-Looking Statements

BioTime cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” project,” “target,” “tend to,” or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to our belief about the ability of OPC1 to act via several distinct mechanisms of action to aid recovery of SCI injury patients, and about the validation of our OPC1 cell therapy program as a result

of the receiving the Notice of Allowance for a patent. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause BioTime's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, without limitation, risk and uncertainties related to: BioTime's ability to raise additional capital when and as needed, to advance its product candidates; BioTime's ability to develop and commercialize product candidates; the failure or delay in starting, conducting and completing clinical trials or obtaining FDA or foreign regulatory approval for BioTime's product candidates in a timely manner; the therapeutic potential of BioTime's product candidates, and the disease indications for which BioTime intends to develop its product candidates; BioTime's ability to conduct and design successful clinical trials, to enroll a sufficient number of patients, to meet established clinical endpoints, to avoid undesirable side effects and other safety concerns, and to demonstrate sufficient efficacy of its product candidates; developments by BioTime competitors that make BioTime's product candidates less competitive or obsolete; BioTime's ability to manufacture its product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture; the performance of third parties in connection with the development and manufacture of BioTime's product candidates, including third parties conducting clinical trials as well as third-party suppliers and manufacturers; the potential of BioTime's cell therapy platform, and BioTime's plans to apply its platform to research, develop and commercialize our product candidates; BioTime's ability, and the ability of its licensors, to obtain, maintain, defend and enforce intellectual property rights protecting BioTime's product candidates, and BioTime's ability to develop and commercialize its product candidates without infringing the proprietary rights of third parties; BioTime's ability to recruit and retain key personnel; and BioTime's ability to successfully integrate the operations of Asterias into BioTime. BioTime's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of BioTime's risks and uncertainties, you are encouraged to review its documents filed with the SEC including its recent filings on Form 8-K, Form 10-K and Form 10-Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. BioTime undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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