BioTime Presents Updated Data from OpRegen® Phase I/IIa Clinical Study at the Association for Research in Vision and Ophthalmology Annual Meeting

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Treatment with OpRegen® Continues to be Well Tolerated with Signs of Structural Improvement in the Retina Observed in Some Patients

ALAMEDA, Calif.--(BUSINESS WIRE)--May 2, 2019-- BioTime, Inc. (NYSE American and TASE: BTX), a clinical-stage biotechnology company developing new cellular therapies, announced that updated results from a Phase I/IIa clinical study of its lead product candidate, OpRegen®, a retinal pigment epithelium (RPE) cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA), will be presented today at the 2019 Association for Research in Vision and Ophthalmology Annual Meeting (ARVO 2019) in Vancouver, BC, Canada. Data from the study demonstrate that treatment with OpRegen continues to be well tolerated and in some patients, signs of structural improvement in the treated areas of the retina have been observed. Of note, early data from Cohort 4 patients with earlier-stage dry-AMD and smaller areas of GA remain encouraging, with indications of the continued presence of the transplanted OpRegen cells and improvements in visual acuity.

Data presented at ARVO 2019 showed that both the surgical procedure and the OpRegen cells were generally well tolerated with no unexpected adverse events or treatment-related systemic serious adverse events reported in the first fifteen patients enrolled to date. The most common and expected ocular adverse events were the formation of mild epiretinal membranes (ERM). One instance of retinal detachment occurred in a patient who was legally blind prior to treatment. The event was not able to be assigned as related to treatment, procedure, or to the combination, and the patient continued in the study following successful surgical repair. One instance of a severe ERM required surgical removal, which was successful, and the subject continues to demonstrate improved visual acuity from baseline following OpRegen administration.

Imaging of several patients from Cohorts 1, 2 and 3, and of particular interest, those from Cohort 4 (n=3) with better baseline vision, demonstrated sustained structural improvement within the retina and evidence of the continued presence of the transplanted OpRegen cells. Within the area of the OpRegen cell transplant, signs of a reduction and change in drusen material, as well as improvements or possible restorations of the ellipsoid zone and RPE layers, have persisted. The photoreceptor layer and ellipsoid zone assumed a more regular structural appearance in areas of the transition zone where OpRegen was administered, suggesting potential structural restoration of the retina in areas receiving the RPE cells. This is of particular importance because in dry-AMD the structure of the retina can be impacted by the formation of excess drusen and ultimately death of RPE cells and photoreceptors, which are critical to sight. Other changes observed following OpRegen treatment persisted through the last time point examined (up to 3 years) and included subretinal pigmentation and hyper-reflective areas seen on optical coherence tomography (OCT). Additionally, asymmetrical, reduced growth of GA in the treated areas receiving OpRegen was observed in some subjects. These observations are being independently evaluated by the Doheny Eye Institute and Doheny Image Reading & Research Lab (DIRRL), Los Angeles, CA.

The Best Corrected Visual Acuity (BCVA) and areas of GA continued to remain largely stable in the treated eyes. Notably, the visual acuity of the first three Cohort 4 patients with better baseline vision have all seen improvements from baseline levels and will be followed for longer periods of time. Overall, OpRegen appears well-tolerated with preliminary evidence of improved structural changes and potential improvement in visual acuity following treatment observed in some patients.

Eyal Banin, MD, PhD, Professor of Ophthalmology, Director, Center for Retinal and Macular Degenerations, Department of Ophthalmology at Hadassah-Hebrew University Medical Center, the presenting author and one of the investigators participating in the study, presented data from the Phase I/IIa clinical study. A copy of Dr. Banin's presentation will be available on the Events section of BioTime's website concurrent with his presentation at ARVO 2019.

About OpRegen®

OpRegen is a RPE transplant therapy in Phase I/IIa development for the treatment of dry AMD, the leading cause of adult blindness in the developed world. OpRegen consists of a suspension of RPE cells delivered subretinally as an intraocular injection. RPE cells are essential components of the back lining of the retina and function to help nourish the retina including photoreceptors. OpRegen has been granted Fast Track designation from the U.S. Food and Drug Administration.

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 the potential improvement in visual acuity following treatment observed in some patients. 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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Source: BioTime, Inc.

BioTime Inc. IR
Ioana C. Hone
(ir@biotimeinc.com)
(510) 871-4188

Solebury Trout IR
Gitanjali Jain Ogawa
(Gogawa@troutgroup.com)
(646) 378-2949