

BioTime Announces First Patient Treated in Pivotal Clinical Trial of Renevia™ for HIV-Associated Lipoatrophy

February 24, 2015

ALAMEDA, Calif.--(BUSINESS WIRE)--Feb. 24, 2015-- BioTime, Inc. (NYSE MKT: BTX) today announced that the first patient was successfully treated in the Company's pivotal clinical trial in Europe assessing the efficacy of *Renevia*™ for the treatment of HIV-associated lipoatrophy. HIV-associated lipoatrophy is a disorder characterized by abnormal loss of body fat from under the skin that occurs in almost half of the approximately three million people on anti-retroviral therapy in the U.S. and Europe. *Renevia* is a proprietary injectable matrix designed to facilitate the stable engraftment of transplanted cells. The uniqueness of *Renevia* is that it allows the mixture of cells with the matrix in a liquid form such that the cells and matrix can be injected easily and safely through a small gauge syringe, and then the matrix can polymerize around the cells to create a three-dimensional tissue within the body.

In the trial, *Renevia* is being tested as a delivery matrix for the patient's own fat-derived cells and injected into portions of the patient's face where there is facial lipoatrophy in order to promote facial tissue reconstruction. The first treatment marks the beginning of enrollment for this pivotal trial and follows the previous successful safety trial of *Renevia*, the completion of which was announced in 2014. The procedure was performed at The Stem Center in Palma de Mallorca, Spain, an innovative patient therapy center and a global leader in clinical research aimed at the use of a patient's adipose derived stem cells for cosmetic and regenerative therapies. The clinical site is located within the Clinica USP Palma Planas hospital in Palma.

"The current options for patients with facial lipoatrophy do not provide a natural long lasting result, so I am excited to be leading this important clinical trial to bring *Renevia* to this community," said Ramon Llull, MD, PhD, Medical Director of The Stem Center and Principal Investigator for the *Renevia* studies. Dr. Llull is a leading expert on advanced regenerative therapies based on lipotransfer.

"The first subject treated in our *Renevia* pivotal trial is a significant clinical milestone for an important BioTime pipeline product," said Adi Mohanty, BioTime's Chief Operating Officer. "*Renevia* is based on our proprietary HyStem® technology platform for cell and molecule transfer, and has the potential to be the first CE-marked injectable delivery vehicle for safe transplantation of therapeutic cells. We are optimistic about the promise of this technology platform because of the potential to solve a major hurdle in the development of effective cell transplant therapies. We believe that meeting the endpoint in our *Renevia* pivotal trial could lead to submission for CE Mark approval in 2016 for HIV related facial lipoatrophy, and could pave the way for other future applications in transplanting other types of cells to address unmet medical needs."

On November 4, 2014, the Spanish Agency of Medicines and Health Products ("AEMPS") authorized BioTime to conduct a randomized, evaluator-blinded, delayed-treatment-controlled study of the effectiveness and safety of *Renevia* as a resorbable matrix for the delivery of autologous adipose-derived cells to treat subcutaneous facial lipoatrophy defects associated with antiviral therapy for HIV infection. The pivotal study will include a minimum of 56 and up to 92 HIV positive males and females between 18-65 years of age. Subjects will be randomized with half in the treatment group and half in a delayed-treatment cohort, each receiving a single treatment procedure of *Renevia*™ with autologous adipose cells harvested by liposuction and implanted in the mid-facial region. The primary effectiveness measure will be the comparison of the change in skin thickness between the treatment and delayed treatment groups. A secondary endpoint will be mid-face volume deficit and global aesthetic improvement scores. Patients will be monitored at one, three, and six-month intervals after treatment. Additional information on the trial will be made available on BioTime's website at www.biotimeinc.com.

About Facial Lipoatrophy and HIV-related Facial Lipoatrophy

Facial lipoatrophy is the loss of facial fat tissue, which is a key component for an overall youthful facial appearance. Facial lipoatrophy is an unfortunate, but inevitable, condition that typically develops as we age but is dramatically accelerated in those HIV-infected individuals being treated with antiretroviral therapy (ART). Indeed the loss of facial fat can be nearly complete in these individuals on ART.

In HIV-infected patients on antiretroviral therapy (ART) facial lipoatrophy is common and particularly devastating. The resulting facial wasting ages the individual's appearance prematurely and, along with a thinning of the skin, allows musculature and vasculature to be easily seen, resulting in what is commonly known as "the face of AIDS." Treatment of the condition has been determined to be medically advisable to improve the individual's self-esteem and quality of life.

Because ART has greatly increased long term survival in HIV-positive patients the incidence of associated lipoatrophy has risen dramatically. According to statistics published by AVERT (www.avert.org), worldwide there were 34 million people living with HIV/AIDS in 2011. According to the World Health Organization (WHO) 10 million of these are receiving ART. That number is expected to grow to 15 million people by the end of 2015.

HyStem® Technology and Renevia™

BioTime's *HyStem*® hydrogels, including *Renevia*, are a family of unique and proprietary biomaterials that are designed to function as adhesion matrices for the stable attachment and survival of cells. The failure rate in many applications of cell grafts without such a matrix is high because of difficulties in achieving cell attachment and survival. The achievement of high success rates for cell grafts would create opportunities to develop cell therapies for many high unmet medical needs. A unique feature of the proprietary technology is that it allows the mixture of cells with the matrix in a liquid form such that the cells and matrix can be injected easily and safely through a small gauge syringe, and then the matrix can polymerize around the cells to create a three-dimensional tissue within the body. The matrix is then resorbed by the body over a few months. *HyStem* hydrogels are currently sold worldwide by BioTime and its distributors for pre-clinical research for a wide array of applications in regenerative medicine including the engraftment of cells in the brain, liver, cartilage and bone, heart, and vocal cords. *Premvia*™, a *HyStem* based hydrogel, is a recently FDA-cleared medical device indicated for the management of wounds. BioTime's *HyStem* technology is covered by two issued US patents with applications pending in the EU, Canada, Japan, and Australia.

About BioTime

BioTime is a biotechnology company engaged in research and product development in the field of regenerative medicine. Regenerative medicine refers to therapies based on stem cell technology that are designed to rebuild cell and tissue function lost due to degenerative disease or injury. BioTime's focus is on pluripotent stem cell technology based on human embryonic stem ("hES") cells and induced pluripotent stem ("iPS") cells. hES and iPS cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products. BioTime's therapeutic and research products include a wide array of proprietary [PureStem](#)[®] progenitors, [HyStem](#)[®] hydrogels, culture media, and differentiation kits. *Renovia*[™] (aHyStem product), is now in a pivotal trial in Europe as a biocompatible, implantable hyaluronan and collagen-based matrix for cell delivery in the treatment of HIV-related lipodystrophy. In addition, BioTime has developed [Hextend](#)[®], a blood plasma volume expander for use in surgery, emergency trauma treatment and other applications. *Hextend* is manufactured and distributed in the U.S. by Hospira, Inc. and in South Korea by CJ HealthCare Corporation, under exclusive licensing agreements.

BioTime is also developing stem cell and other products for research, therapeutic, and diagnostic use through its subsidiaries:

- [Asterias Biotherapeutics](#), Inc. is developing pluripotent stem-cell based therapies in neurology and oncology, including AST-OPC1 oligodendrocyte progenitor cells in spinal cord injury, multiple sclerosis and stroke, and AST-VAC2, an allogeneic dendritic cell-based cancer vaccine. Asterias Series A common stock is traded on the NYSE MKT under the symbol AST.
- BioTime Asia, Ltd., a Hong Kong company, may offer and sell products for research use for BioTime's ESI BIO Division.
- [Cell Cure Neurosciences](#) Ltd. is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders. *OpRegen*[®] is currently in a Phase I/IIa clinical trial for the treatment of the dry-form of age-related macular degeneration.
- [ESI BIO](#) is the research and product marketing division of BioTime, providing stem cell researchers with products and technologies to enable them to translate their work into the clinic, including *PureStem*[®] progenitors and *HyStem*[®] hydrogels.
- [LifeMap Sciences](#), Inc. markets, sells, and distributes [GeneCards](#)[®], the leading human gene database, as part of an integrated database suite that also includes the [LifeMap Discovery](#)[®] database of embryonic development, stem cell research, and regenerative medicine, and [MalaCards](#), the human disease database.
- [LifeMap Solutions](#), Inc. is a subsidiary of LifeMap Sciences focused on developing mobile health (mHealth) products.
- [OncoCyte](#) Corporation is developing products and technologies to diagnose and treat cancer, including *PanC-Dx*[™], with four clinical studies currently underway.
- [OrthoCyte](#) Corporation is developing therapies to treat orthopedic disorders, diseases and injuries.
- [ReCyte Therapeutics](#), Inc. is developing therapies to treat a variety of cardiovascular and related ischemic disorders, as well as products for research using cell reprogramming technology.

BioTime common stock is traded on the NYSE MKT under the symbol BTX. For more information, please visit www.biotimeinc.com or connect with the company on [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#), and [Google+](#).

Forward-Looking Statements

Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for BioTime and its subsidiaries, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of BioTime and its subsidiaries, particularly those mentioned in the cautionary statements found in BioTime's Securities and Exchange Commission filings. BioTime disclaims any intent or obligation to update these forward-looking statements.

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