BioTime Submits CE Mark Application for European Approval of Renevia®

March 13, 2018

ALAMEDA, Calif.--(BUSINESS WIRE)--Mar. 13, 2018-- BioTime, Inc. (NYSE American: BTX), a clinical-stage biotechnology company focused on addressing degenerative diseases, announced today the submission of a design dossier application for CE Mark approval to market Renevia® in Europe. BioTime anticipates CE Mark approval in the second half of 2018.

“Submission of the CE Mark application establishes an important milestone for BioTime and we are delighted with the achievements made in the clinical performance of Renevia, as demonstrated in the pivotal trial,” said Adi Mohanty, Co-Chief Executive Officer of BioTime. “We look forward to approval in the EU and, provided appropriate clinical data support, expanding the label into other indications and geographies, including the U.S.”

The CE Mark application was based on Renevia® successfully meeting its primary endpoint with treated patients retaining approximately 100% of transplanted volume at six months. In addition to strong product performance at 6 months, treated patients retained an average 70% of the transplanted volume at 12 months and 64% at 18 months. All Renevia® transplants were shown to be generally well tolerated and there were no device-related serious adverse events noted during this trial.

BioTime views the European pivotal trial in HIV-associated lipoatrophy as an entryway into a larger market opportunity, like cosmetic facial aesthetics. Currently, the cosmetics facial aesthetics market is estimated to be over 5 billion dollars and growing at or near double digits. Exploration of Renevia®s performance (known as Premvia™ in the U.S.) into the broader facial aesthetics market has already begun with an investigator-led trial in the U.S. This ongoing facial aesthetics trial is being conducted by Dr. Joel A. Aronowitz, who is a leading Beverly Hills plastic surgeon.

In combination with the U.S. investigator-led trial, we believe we can build upon the European trial data with additional appropriate clinical evidence to expand the potential utility of Renevia® and enter other geographies, including the U.S.

About Renevia®

Renevia® is an investigational medical device that is being developed as an alternative for whole adipose tissue transfer (fat grafting) procedures. Renevia® is part of the Hystem® hydrogel family of proprietary injectable matrices, being developed as devices for wound management, cell and drug delivery.

About Premvia™

Approved Uses

Premvia™ is indicated for the management of wounds including: partial-thickness, full-thickness, tunneling wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, donor skin graft sites, post-Moh’s surgery, post-laser surgery, podiatric wounds, wound dehiscence, abrasions, lacerations, second degree burns, skin tears, and draining wounds.

Contraindications

- Premvia™ is contraindicated for patients with severe allergies, indicated by a history of anaphylaxis or presence of multiple severe allergies.
- Premvia™ is specifically contraindicated for patients with known allergies to products containing either hyaluronan or collagen derivatives.
- Premvia™ is not indicated for use in third degree burns.

Important Safety Information

- Complications that may arise from wound management products may include: infection, chronic inflammation, allergic reaction, excessive redness, pain, or swelling. If any of these complications are present, product should be removed from the wound area.
- Federal law restricts this device to sale by or on the order of a physician or practitioner.
- Only the vial contents are sterile – outside of vials are not sterile.
- Do not add additional components or additives to Premvia™.

About BioTime, Inc.

BioTime is a clinical-stage biotechnology company focused on degenerative diseases. Its clinical programs are based on two platform technologies: cell replacement and cell/drug delivery. With its cell replacement platform, BioTime is creating new cells and tissues with its proprietary pluripotent cell technologies. These cells and tissues are developed to replace those that are either rendered dysfunctional or lost due to degenerative diseases. BioTime’s cell/drug delivery programs are based upon its proprietary HyStem® cell and drug delivery matrix technology. HyStem® was designed to provide for the transfer, retention, engraftment and metabolic support of cellular replacement therapy. BioTime’s lead cell delivery clinical program, Renevia®, which consists of our proprietary HyStem® cell-transplantation delivery matrix combined with the patient's own adipose progenitor cells (Fat), met its primary endpoint in an EU pivotal clinical trial for the treatment of facial lipoatrophy in HIV patients in 2017. Submission for approval of

Renevia® in the EU occurred in the second quarter of 2018, with possible approval in 2018. There were no device related serious adverse events reported to date. Our lead cell replacement clinical program, OpRegen®, which is a retinal pigment epithelium transplant therapy, is in a Phase I/IIa multicenter trial for the treatment of dry age-related macular degeneration, the leading cause of blindness in developing countries. There were no related serious adverse events reported to date. BioTime also has significant equity holdings in two publicly traded companies, Asterias Biotherapeutics, Inc. (NYSE American: AST) and OncoCyte Corporation (NYSE American: OCX), and a private company, AgeX Therapeutics, Inc.

BioTime common stock is traded on the NYSE American and TASE under the symbol BTX. For more information, please visit www.biotime.com or connect with the company on Twitter, LinkedIn, Facebook, YouTube, and Google+.

To receive ongoing BioTime corporate communications, please click on the following link to join the Company's email alert list: http://news.biotime.com.

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Source: BioTime, Inc.

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