BioTime Receives Approval to Begin Human Clinical Trials of Renevia

Business Wire

BioTime, Inc. today announced that it has received approval from The Spanish Agency of Medicines and Medical Devices (AEMPS) to begin human clinical trials of Renevia™, a unique biomaterial used as a delivery matrix for autologous adipose derived cells to treat the loss of subcutaneous adipose tissue (lipoatrophies) arising from trauma, surgical resection, and congenital defects and disease. This AEMPS approval follows the earlier approval this year from the Balearic Island Ethics Committee Approval for the first of a multiphase clinical investigation of Renevia™.

The clinical studies will be conducted at The Stem Center in Palma de Mallorca, Spain, an innovative patient therapy center, laboratory, and professional research facility located within the Clinica USP Palma Planas hospital in Palma. The Medical Director of The Stem Center and Principal Investigator for the Renevia studies, Ramon Lull, MD, PhD, is a leading expert on advanced regenerative therapies based on adipose technology. The Stem Center is owned and operated by the GID Group, Inc., Louisville, CO, USA.

BioTime expects that the first clinical investigation, a study in 10 volunteers to demonstrate the safety of Renevia™ in humans, will be completed before the end of the year. Subsequent clinical studies are being planned to document the efficacy of Renevia™ as a delivery matrix for autologous adipose cells to restore normal skin contours in patients where the subcutaneous adipose tissue had been lost to lipoatrophy. Commenting on the approval, Dr. Lull, said, “The desire for a new and effective delivery matrix allowing for easier placement and potentially superior grafting of autologous cells is high. We are looking forward to getting started testing this novel biomaterial.” Renevia™ is manufactured in the US in compliance with cGMP requirements and has been tested pursuant to ISO 10993 standards for Class III implantable medical devices. In these studies Renevia™ has been shown to be biocompatible.

Commenting on the AEMPS approval to begin clinical investigations, William, P. Tew, PhD, BioTime’s Chief Commercial Officer, said “We are delighted to begin this next phase in our program for obtaining a CE Mark for Renevia™. We have developed Renevia™ to provide plastic and reconstructive surgeons a safe and effective delivery matrix for tissue engineering and regenerative medicine applications utilizing autologous adipose cells.” Renevia™ is a member of BioTime’s HyStem® family of hydrogels. These unique biomaterials are designed as matrices and scaffolds for cell delivery in a wide variety of medicine applications. HyStem® hydrogels are distributed and sold worldwide by BioTime and its distributors for pre-clinical research. BioTime’s HyStem® technology is covered by two issued US patents with applications pending in the EU, Canada, Japan, and Australia.

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