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Stem cell 'vehicle' gets human trial approval in Spain

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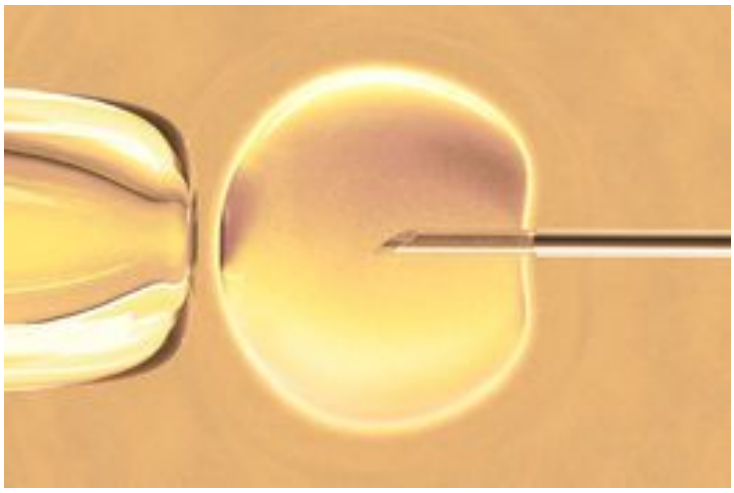

Singapore: Stem cell focused firm BioTime has received approval from Spanish Agency of Medicines and Medical Devices (AEMPS) to begin human clinical trials of Renevia.

Renevia is an unique biomaterial that has as a delivery matrix and can be used as a vehicle for placing autologous adipose derived cells. It can be used to treat the loss of subcutaneous adipose tissue (lipoatrophies) arising from trauma, surgical resection, and congenital defects and disease.

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, Dr Ramon Lull, is an expert on advanced regenerative therapies based on adipose technology.

BioTime expects that the first clinical investigation, which will be a study conducted in 10 volunteers in order to demonstrate the safety of Reneviain humans, will be completed before the end of the year. Subsequent clinical studies are being planned to document the efficacy of Reneviain 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."