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FDA approves stem cell trial for multiple sclerosis

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Singapore: Tisch MS Research Center of New York has received Investigational New Drug (IND) approval from the Food and Drug Administration (FDA) to commence a phase I trial using autologous neural stem cells in the treatment of multiple sclerosis (MS).Ã?Â

"To my knowledge, this is the first FDA-approved stem cell trial in the US to investigate direct injection of stem cells into theÃ?Â cerebrospinal fluid of MS patients, and represents an exciting advance in MS research and treatment," said Dr Saud A Sadiq, senior research scientist at Tisch MS Research Center of New York and the study's principal investigator.

The groundbreaking study will investigate a regenerative strategy using stem cells harvested from the patient's own bone marrow. These stem cells will be injected intrathecally (into the cerebrospinal fluid surrounding the spinal cord) in 20 participants who meet the inclusion criteria for the trial. This will be an open label safety and tolerability study. All study activities will be conducted at the Tisch MS Research Center and affiliated International Multiple Sclerosis Management Practice (IMSMP).

The clinical application of autologous neural progenitors in MS is theÃ?Â culmination of a decade of stem cell research conducted by a dedicated teamÃ?Â of scientists headed by Dr Sadiq and by Dr Violaine Harris, research scientist at Tisch MS Research Center. Preclinical testing found that the injection of these cells may decrease brain inflammation and promote myelin repair and/or neuroprotection. "This study exemplifies the Tisch MS Research Center's dedication to translational research and provides a hope that established disability may be reversed in MS," Dr Sadiq noted.Ã?Â

Participants will undergo a single bone marrow collection procedure, from which mesenchymal stem cell-derived neural progenitor cells (MSC-NPs) will be isolated, expanded and tested prior to injection. Participants will receive three rounds of injections at three month intervals. Safety and efficacy parameters will be evaluated in all participants through regular follow-up visits.