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FDA ADVISES TISCH MS RESEARCH CENTER TO MARCH ON: PREPARATION TO BEGIN FOR PHASE II OF STEM CELL TRIAL FOR MS

Encouraging Results from Phase I Show Reversal of Disability and Repair of Damage Caused by Multiple Sclerosis

New York, NY - January 13, 2016 - <u>Tisch MS Research Center of New York</u> (<u>Tisch MSRCNY</u>) announced today that it will pursue Phase II of its clinical trial, the first stem cell treatment for MS in the United States ever to move to this stage. Following the establishment of safety and tolerability in Phase I with no adverse effects, the Food and Drug Administration (FDA) advised Tisch MSRCNY to continue with its research.

"Our unprecedented <u>Phase I results</u> have propelled us into the next phase of research," said Dr. Saud A. Sadiq, Chief Research Scientist at Tisch MSRCNY and the study's principal investigator. He added, "No treatment has shown reversal of established disability in MS until now. The objective improvement experienced in bladder function, vision and walking speed in both secondary and primary progressive MS is remarkable. We now plan to establish efficacy of stem cells as a reparative therapy in Phase II."

The Phase II trial will be a double-blind, placebo-controlled, randomized trial with forty patients in a crossover design. Stem cells are taken from the patient's bone marrow and manipulated to become brain-like neuronal cells, a process created and found only at Tisch MSRCNY. All treatments and research will be conducted at the Tisch MS Research Center of New York and will expand to include an additional leading MS center.

The main obstacle in initiating the study is the need for critical funding. Once funding is obtained, patients will be recruited and the study is anticipated to commence in the summer of 2016.

About Tisch MS Research Center of New York

For over twenty years, <u>Dr. Saud A. Sadiq</u> has believed that combining clinical excellence with innovative research targeted at finding the cure for multiple sclerosis would set an exemplary standard for healthcare. Today, Tisch MS Research Center of New York embodies this new model. The close relationship of the non-profit research center and its affiliated clinical practice, the <u>International Multiple Sclerosis Management Practice</u>, enables the testing of new MS treatments and accelerates the pace at which research discoveries move from lab bench to bedside. Tisch MS Research Center of New York aims to find the cause of MS, optimize treatments for patients, and repair the damage caused by multiple sclerosis.

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