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Cells from placentas safe for patients with multiple sclerosis

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Patients with Multiple Sclerosis (MS) were able to safely tolerate treatment with cells cultured from human placental tissue, according to a study published today in the journal *Multiple Sclerosis and Related Disorders*. The study, which is the first of its kind, was conducted by researchers at Mount Sinai, Celgene Cellular Therapeutics subsidiary of Celgene Corporation and collaborators at several other institutions.

While designed to determine safety of the treatment, early signals in the data also suggested that a preparation of cultured cells called PDA-001 may repair damaged nerve tissues in patients with MS. PDA-001 cells resemble "mesenchymal," stromal stem cells found in connective tissue in bone marrow, but unlike their bone-marrow derived counterparts, stromal cells from the placenta are more numerous, with one donor able to supply enough cells for many patients.

"This is the first time placenta-derived cells have been tested as a possible therapy for multiple sclerosis," said Fred Lublin, MD, Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Professor of Neurology at Icahn School of Medicine at Mount Sinai and the lead investigator of the study. "The next step will be to study larger numbers of MS patients to assess efficacy of the cells, but we could be looking at a new frontier in treatment for the disease."

MS is a chronic autoimmune disease in which the body's immune system mounts recurring assaults on the myelin—the fatty, protective coating around nerve fibers in the central nervous system. This causes nerves to

malfunction and can lead to paralysis and blindness. The disease usually begins as an episodic disorder called relapsing-remitting MS (RRMS), and for many sufferers, evolves into a chronic condition with worsening disability called secondary progressive MS (SPMS).

The new safety study was conducted on 16 MS patients (10 with RRMS and six with SPMS) between the ages of 18 and 65. Six patients were given a high dose of PDA-001, another six were given a lower dose, and four patients were given placebo. Any time the immune system is altered, say by an experimental treatment, there is always a risk for MS to worsen, noted Dr. Lublin. All subjects were given monthly brain scans over a six-month period to ensure they did not acquire any new or enlarging brain lesions, which would indicate a worsening of MS activity. No subjects showed any paradoxical worsening on MRI and after one year, the majority had stable or improved levels of disability.

"We're hoping to learn more about how placental stromal cells contribute to myelin repair," said Dr. Lublin. "We suspect they either convert to a myelin making cell, or they enhance the environment of the area where the damage is to allow for natural repair. Our long-term goal is to develop strategies to facilitate repair of the damaged nervous system."

Provided by The Mount Sinai Hospital

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