Feds OK 2nd human study of embryonic stem cells

MALCOLM RITTER - AP Science Writer - Associated Press

For only the second time, the U.S. government has approved a test in people of a treatment using embryonic stem cells — this time for a rare disease that causes serious vision loss.

Advanced Cell Technology, a biotechnology company based in Santa Monica., Calif., said the research should begin early next year, following the green light from the U.S. Food and Drug Administration.

Just last month another biotech company, Geron Corp., said it had begun preliminary testing in people for treating spinal cord injuries by injecting cells derived from embryonic stem cells.

Scientists hope to use stem cells to create a variety of tissues for transplant. But human embryos have to be destroyed to harvest those cells, which has made their use controversial.

ACT's experiment will focus on Stargardt disease, which affects only about 30,000 Americans. But the company hopes the same approach will work for similar and more common eye disorders like age-related macular degeneration, which affects millions.

Stargardt is an inherited disorder that attacks central vision used for tasks like reading and recognizing faces. Some patients go totally blind, even losing peripheral vision, while others are severely impaired and can only perceive light or see their hands moving in front of their faces.

The disease typically starts in adolescence. The key problem is that impaired scavenger cells fail to remove toxic byproducts from the eye, allowing them to build up and kill other cells. There is no proven treatment.

In the new study, 12 patients will be treated with healthy scavenger cells, created in a laboratory from human embryonic stem cells. This early phase of the research is primarily to test the safety of various doses, injecting only one eye of each patient.

"We're also hoping to see some improvement in visual acuity, but that's a bonus," said Dr. Robert Lanza, ACT's chief scientific officer.

The research will be performed at medical centers in Massachusetts, New Jersey and Oregon, ACT said.

Stephen Rose, chief research officer of the Foundation Fighting Blindness, said his

group is "very, very glad" that ACT has permission to begin the study.

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Online:

ACT: http://www.advancedcell.com

Stargardt disease: http://bit.ly/bioNHS

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