



January 23, 2009

First embryonic stem cell study to start

FDA approves firm's ground-breaking research of treatment for spinal injuries, set to begin in summer.

By: MALCOLM RITTER

NEW YORK -- A U.S. biotech company says it plans to start this summer the world's first study of a treatment based on human embryonic stem cells -- a long-awaited project aimed at spinal cord injury.

The company gained federal permission this week to inject eight to 10 patients with cells derived from embryonic cells, said Dr. Thomas Okarma, president and CEO of Geron Corp. of Menlo Park, Calif.

The patients will be paraplegics, who can use their arms but can't walk. They will receive a single injection within two weeks of their injury.

The study is aimed at testing the safety of the procedure, but doctors will also look for signs of improvement like return of sensation or movement in the legs, Okarma said.

Whatever its outcome, the study will mark a new chapter in the contentious history of embryonic stem cell research in the United States -- a field where debate spilled out of the laboratory long ago and into national politics.

While some overseas doctors claim to use human embryonic stem cells in their clinics, stem cell experts said they knew of no previous human studies that use such cells.

"It's a milestone and it's a breakthrough for the field" because Geron passed the safety hurdles for getting federal clearance to launch the study, said Ed Baetge, chief scientific officer of Novocell Inc. His company hopes to begin a similar human study for treating diabetes in a few years.

In addition, said spinal cord injury researcher Dr. Wise Young of Rutgers University, "a lot of hope of the spinal cord injury community is riding on this trial."

Embryonic stem cells can develop into any cell of the body, and scientists have long hoped to harness them for creating replacement tissues to treat a variety of diseases. But research has been controversial because embryos must be destroyed to obtain them.

President Barack Obama has promised to relax the Bush administration's restrictions on federal financing for such research. But Obama's ascent to the White House had nothing to do with the U.S. Food and Drug Administration's granting permission for the new study, Okarma said in a telephone interview Thursday.

In fact, the company says, the project involves stem cells that were eligible for federal funding under Bush, although no federal money was used to develop the experimental treatment or to pay for the human study.

Other human cells, called adult stem cells, have been tested before in people to treat heart problems, for example.

In the Geron study, the injections will be made in the spine at the site of damage. The work will be done in four to seven medical centers around the country, Okarma said.

Animal studies suggest that once injected, the cells will mature and repair what is essentially a lack of insulation around damaged nerves, and also pump out substances that nerves need to function and grow.