

Study Using Embryonic Stem Cells Is Delayed

By BLOOMBERG NEWS

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The Geron Corporation said on Tuesday that regulators had held up its study of a therapy for injured spinal cords before even one patient could be enrolled, delaying the first human trial using embryonic stem cells.

The halt was ordered after Geron shared data from dose escalation studies in animals with the Food and Drug Administration, the company said. The therapy is meant to restore movement to paralyzed people by injecting nerve cells made from embryonic stem cells to the site of the injury.

In January, the F.D.A. lifted a delay on the clinical trial from May 2008. The action on Tuesday was probably based on safety concerns that emerged from the new higher-dose data the company had submitted, said Joseph Pantginis, an analyst with the Merriman Curhan Ford Group in New York.

“They are at the forefront, which a lot of times is a bit of a curse,” Mr. Pantginis said. “They have to hit all the hurdles and be the first one to learn about how these cells behave.”

Geron “will work closely with the F.D.A. to facilitate their review of the new data and to release the clinical hold,” the company said.

Geron, based in Menlo Park, Calif., had no further comment, said Anna Krassowska, a spokeswoman.

While thousands of patients around the world have been treated with adult stem cells and have shown mixed results, no humans have been given cells derived from embryos in an approved trial.