FDA OKs First Embryonic Stem Cell Research Trial on Humans, Despite Concerns

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Washington, DC (LifeNews.com) -- The Obama administration has approved the bid by cloning company Geron to undertake the first trial involving the use of embryonic stem cells in humans. They have never been used before in people because the cells cause tumors and have been plagued by immune system rejection issues when tried in animals.

Scientists and pro-life advocates say human embryonic stem cells are not ready for trial because problems associated with the cells in animals haven't been solved.

The Food and Drug Administration had initially placed the trial on hold but Geron indicated today that the agency is now allowing it to proceed with an early stage trial on a stem cell therapy for acute spinal cord injury.

The FDA placed a hold on the trial last August, when evidence showed Geron's GRNOPC1 encountered safety issues when used in animal studies. Geron's own data showed higher frequency of small cysts within the injury site in the spinal cord of animals injected with the embryonic cells.

“We are pleased with the FDA’s decision to allow our planned clinical trial of GRNOPC1 in spinal cord injury to proceed,” said Thomas B. Okarma, Geron's president, in a public statement today. The company's stock rose in value following the announcement.

Previously, Dr. John A. Kessler, chairman of neurology and director of the stem cell institute at Northwestern University, said the first application from Geron for the embryonic stem cell trial was flawed.

“We really want the best trial to be done for this first trial, and this might not be it,’’ he said at the time.

Responding to the news today, Dr. David Prentice, a former biology professor at Indiana State University who is now a fellow at the Family Research Council, tells LifeNews.com those concerns should still exist.

"It's unfortunate that the FDA has released Geron from the safety hold on their embryonic stem cell trial," he said. "Even many pro-embryonic stem cell scientists have expressed reservations about Geron's trial, that it is not proven even in rats. The concern for many of us is that Geron is endangering patient's health and very lives, to make a political point and increase their stock price."

Prentice also said the trial's approval makes it so the use of adult stem cells, which are safely helping patients battling more than 100 diseases and conditions already, continue to be ignored.

"In the meantime, adult stem cells have already shown published scientific evidence for safety and successful repair of spinal cord injury in patients. Only adult stem cells offer both an ethical and successful path to healing," he said.

Prentice also explained that the trial isn't precisely the first one involving embryonic stem cells -- making it so media outlets need to fully explain what Geron is doing.

"They inject cells derived from embryonic stem cells; in this case a cell type called an oligodendrocyte, which is a cell that forms a sheath, like insulation, around nerve fibers," he said. "So they don't inject growing embryonic stem cells, but the cells are indeed directly derived from embryonic stem cells, and actually are not completely differentiated, but only part-way ("precursors")."

"The theory is that once inside the body, the cells will finish specializing to the final cell type, and form an insulative covering over exposed nerves in the spinal cord," he told LifeNews.com.

Last August, Evan Snyder, a neuroscientist who heads up the stem cell research center at the Burnham Institute for Medical Research in San Diego, warned the research may not be ready for humans.

"There's a lot of debate among spinal cord researchers that the pre-clinical data itself doesn't justify the clinical trial," Snyder, who is working on using neural stem cells himself, says.

Snyder says the mice Geron used to conduct pre-human trial research had more excessive injuries that scientists would normally prefer to see prior to trying the procedure on human patients.

He suggests that Geron should have done experiments involving larger animals before seeking FDA permission to use the controversial embryonic stem cells in humans.

Those concerns existed as early as 2005 and may not have been addressed.

Snyder said then that Geron should do more animal testing first to make sure the tests would be on the same injuries humans have.

"I'm not convinced they have done that yet," Snyder said.

Jerry Silver, a neuroscience professor and stem-cell researcher at Case Western Reserve University in Cleveland, told Knight Ridder back in November 2005 that Geron was moving too fast and needed to do more tests on animals before seeking human patients.

"Frankly, I cannot conceive of a human trial with the use of human embryonic stem cells following immediately from experiments in rodents only," he said then. "Many treatments that work in rodents to alleviate disease fail miserably in humans."

Geron came under criticism earlier this year when news surfaced that the application Geron Corporation submitted to the FDA to become the first to engage in human trials of embryonic stem cells was timed with a trigger to make it so it would be considered during the Obama administration. The cloning company worried it would not be approved during the administration of President George W. Bush.

Just days after Obama took office, the FDA suddenly decided to approve Geron's application for the controversial study.
