

## Stem Cell Trial Nearly a Go?

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The first clinical trial treatment based on embryonic stem cells may soon get the go ahead.

In May, the Food and Drug Administration placed a hold on a clinical trial application submitted by Geron Corporation, a California-based biotech. The company submitted a 22,500-page Investigational New Drug application to the FDA for an embryonic stem cell-derived compound -- called GRNOPC1 -- to treat spinal cord injury.

Geron president and CEO, Tom Okarma, said at the New York Stem Cell Foundation conference at Rockefeller University on Wednesday (October 15) that the company has had to “educate” the FDA on all the procedures used to grow, quantify, and characterize their stem cell populations. He added that there is no evidence of political pressures behind the hold, and he thinks the FDA did the right thing to hold the trial, in order to get a grasp on the science and ensure safety.

But the FDA is nearing the end of its review process and may lift the hold and allow clinical trials to commence within the next three months, Okarma told The Scientist. “We’ve got our arms wrapped around it,” he added. “It’s been a long education process.”