



Market Scan

Geron's Giant Leap

Biopharma's shares soar after getting FDA approval on the first-ever human trial of embryonic stem cell therapy.

By Lisa LaMotta

The change has already begun. Just two days after his inauguration, President Barack Obama is set to clear the way for the first human testing of embryonic stem cells on people with spinal injuries, and biopharmaceutical firms like Geron are set to benefit.

Geron (nasdaq: GERN - news - people) announced Friday that it had received approval from the U.S. Food and Drug Administration for testing of its GRNOPC1 in patients with acute spinal cord injury, sending its shares up 56.8%, or \$2.96, to \$8.17.

GRNOPC1 uses living stem cells to reinsulate and stimulate function in nerves, leading to the restoration of function in the nerve cells of the spinal cord. The early stage human study will test the safety of the process. While the goal of the study is to show safety, it will also be looking at whether GRNOPC1

improves neuromuscular control or if it improves sensation in the lower extremities.

"This marks the beginning of what is potentially a new chapter in medical therapeutics--one that reaches beyond pills to a new level of healing: the restoration of organ and tissue function achieved by the injection of healthy replacement cells," said Geron's Chief Executive Thomas Okarma, Ph.D., M.D. "If safe and effective, the therapy would provide a viable treatment option for thousands of patients who suffer severe spinal cord injuries each year."

Needham analyst Mark Monane expects Geron to take the next 10 months to enroll people in the study. He anticipates that Geron will report data from the study throughout 2009.

Obama recently promised to lift former President Bush's ban on

federal funding of certain areas of stem cell research, particularly that involving human embryonic stem cells. If such a change is signed into law, this controversial area of science will present the legal community with a new challenge.

Intellectual property lawyer Kent Cheng, a partner in the firm of Cohen Pontani Lieberman & Pavane LLP, told Forbes that the ban lifting would, of course, provide more government funding to stem cell research.

He added that this should increase the number of patents covering stem cell-related inventions. It also would give the government more control over who owns and is licensed under critical patents in the field and help bring products to market faster than if they were controlled by a few corporations.