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First Embryonic Stem-Cell Trial Gets Approval From the FDA

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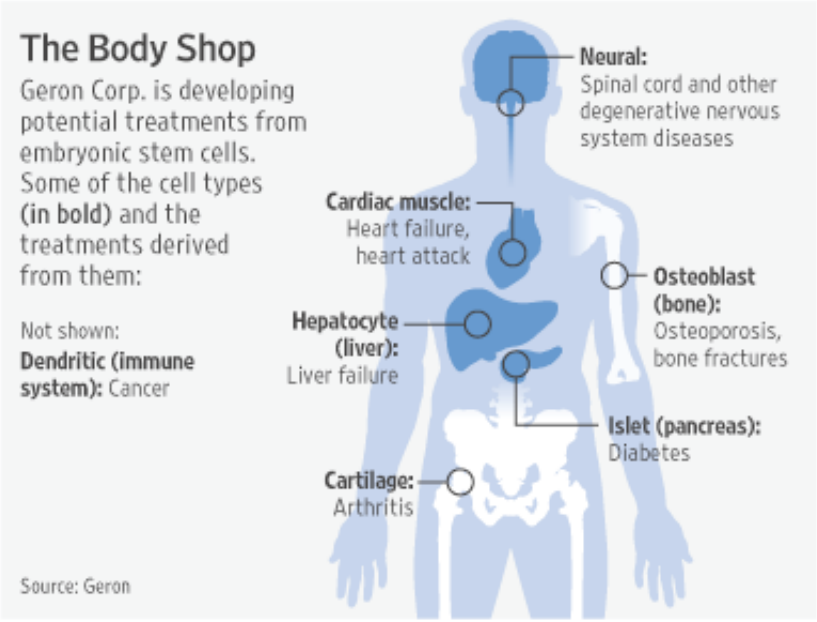
In a watershed moment for one of the most contentious areas of science and American politics, the U.S. Food and Drug Administration cleared the way for the first-ever human trial of a medical treatment derived from embryonic stem cells.

Geron Corp., a Menlo Park, Calif., biotechnology company, is expected to announce Friday that it received a green light from the agency to mount a study of its stem-cell treatment for spinal cord injuries in up to 10 patients. The announcement caps more than a decade of advances in the company's labs and comes on the cusp of a widely expected shift in U.S. policy toward support of embryonic stem-cell research after years of official opposition.

"This is the dawn of a new era in medical therapeutics," said Thomas B. Okarma, Geron's president and chief executive officer. The hope that stem-cell therapy will repair and regenerate diseased organs and tissue "goes beyond what pills and scalpels can ever do."



Limits on stem-cell research, which prevented federal funding and were imposed by Congress and former President George W. Bush for ethical and religious reasons, have had a chilling effect on both academic and corporate research involving such cells. Proponents of stem-cell research say restrictions have delayed development of promising new treatments, while critics contend that harvesting stem cells from embryos destroys human life.

President Barack Obama said during his campaign that overturning research limits would be a top priority in his administration.

Both Geron and the FDA said the timing of the decision to approve the study was coincidental. "The FDA looks to the science on these types of issues, and we approve [such applications] based on a showing of safety," said Karen Riley, an FDA spokeswoman. "Political considerations have no role in this process."

Approval of the study is far from a guarantee that stem-cell treatments will work or make it to the market, but it is likely to be seen as an indication that opportunities for stem-cell research are poised to open and will fuel enthusiasm among academic and corporate researchers.

Mr. Obama's plans for acting on the current research restrictions haven't been finalized. Shortly after the election, Obama advisers thrilled biotech companies and investors when they suggested that the new president could use his executive authority to undo the Bush administration ban. But in a Jan. 18 interview on CNN, Mr. Obama said he might let Congress take the lead. "I like the idea of the American people's representatives expressing their views on an issue like this," he said.

Regulating stem-cell therapy is new turf for both industry and the FDA, a major reason why it took the agency nearly a year to review Geron's 21,000-page application for the trial, which it filed last March. Approval came in a phone call Wednesday afternoon, Dr. Okarma said.

The study will focus on the safety of the treatment. At an FDA hearing in April, several firms' executives and researchers complained that they were at a loss about what the FDA wanted in terms of clinical trials involving stem cells because the FDA itself wasn't sure.

Embryonic stem cells are the building-block cells that help drive prenatal development. Geron has developed banks of embryonic stem cells and found a way to coax them into differentiating as they do in nature into progenitors of specific cells that make spinal-cord tissue, heart muscle, cartilage and other organs and tissues.

Spinal-cord injury is one of medicine's most debilitating conditions, typically causing paralysis and other issues for which there are few, if any, effective treatments. The Geron study will enroll paralyzed patients who can be treated within 14 days of their injury. Patients will be evaluated for at least one year, after which, if the treatment proves safe, the company hopes to increase the dose and expand the potential candidates for the therapy.

In addition to safety, researchers will look for signs that the treatment is effective.

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