



## Embryonic stem cells trial on track to start

By Clive Cookson in Boston

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The first clinical trial of embryonic stem cells is on track to start early next year on patients with spinal cord injury. Geron, the California-based biotechnology company, will carry out the study on accident victims in six trauma centres across the US.

“The world’s spotlight will be on this trial,” Tom Okarma, Geron’s chief executive, told the Bio conference in Boston. To get it right, the company has carried out several years of preparatory work in collaboration with its academic partners at the University of California, Irvine.

Geron’s product will have been tested in 2,000 animals before it goes into its first patient, Mr Okarma said. It consists of immature oligodendrocytes – specialised nerve cells – grown from human embryonic stem cells. The animal tests show that these can repair spinal cord injuries in rats, by growing new nerves with the myelin sheaths they need to work properly. Paralysed rats can walk again.

Mr Okarma said the product was designed to repair recent spinal damage and would need to be injected into patients within two weeks of the accident. It could not help people with long-term paralysis such as the late actor Christopher Reeve who did so much to champion stem cell research for spinal injury.

Because the first application for a human embryonic stem cell trial is bound to receive extraordinary scrutiny from the US Food and Drug Administration, Geron is working closely with FDA officials to smooth the path in advance of the submission. The embryonic stem cells are already qualified for human therapeutic use, after exhaustive tests showed that the cell cultures contain no contamination with animal proteins or viruses.

Mr Okarma pointed out that human embryonic stem cell research was less than 10 years old; the first such cells were produced at the University of Wisconsin in 1998. “With breakthrough therapies such as antibodies and genetic engineering there is usually a 10 to 20 year period of government funding academic research that improves upon the basic invention before industry can put its toes in,” he said.

That has not happened with stem cells because of the Bush Administration’s federal funding restrictions. As a result, Mr Okarma said, “we have to pay the bill for every academic collaboration – and that is not sustainable.”

Hans Kierstead, head of the embryonic stem cell team at UC Irvine, was worried about the high level of public expectation. “I find it unfair that people demand so much from such a young field,” he said. “Just look at the strides we have already made.”

Bob Klein, architect of California's Proposition 71 authorising the state to spend at least \$3bn over 10 years on stem cell research, also told the Bio conference of his concern about excessive expectations. "In clinical trials there will inevitably be failures as well as successes," he said.

"The ideological right is not asleep," said Mr Klein, who chairs California Institute of Regenerative Medicine's governing board. "They will be prepared to spin [any problems] to promote their opposition to embryonic stem cell research, and we'll need a sophisticated fast-response messaging team to put across our message."

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