

The following excerpts are from a story written by *Crain's Detroit Business* reporter, Tom Henderson, published in *Crain's Detroit Business* on August 1, 2014.

It has been an interesting week, to say the least, for stem-cell researcher Eva Feldman, M.D., director of the **A. Alfred Taubman Medical Research Institute** at the **University of Michigan** and director of the ALS clinic at the school's health system.

Between appointments, meetings and time in the lab, she was making tweaks suggested by the **National Institutes of Health** on her \$5 million grant proposal for the organization to fund Phase 2b and Phase 3 human trials on patients with ALS, or Lou Gehrig's disease.

Feldman was also studying results of her group's just-concluded first trial of stem-cell injections in mice with Alzheimer's disease, results that she said exceeded her expectations. If all goes well, this research could lead to approved treatments to improve cognitive function of those suffering from the devastating disease.

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Thursday, the last of 15 operations on ALS patients in the Phase 2a part of the human trials — involving the injection of 8 million embryonic stem cells in the cervical region and another 8 million in the lumbar region — was performed at **Emory University Hospital** in Atlanta.

Feldman hopes to begin the next part of the trials, which will involve 32 ALS patients, in January or February. Meanwhile, tests will continue of the 15 patients in the Phase 2a trial to determine how the injection of the stem cells slows down the progression of the disease.

“So far, there appears to be a prominent signal in patients slowing a progression in the disease,” she said. The first of the patients was operated on last October.

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Six of the 15 Phase 2a operations were conducted at UM, three at Harvard and nine at Emory.

Emory and UM will be the main sites for the next 32 operations, with the NIH going to recommend one hospital on the West Coast and another on the East Coast, said Feldman.

She will need to raise matching funds of \$2.5 million from philanthropies and foundations, but doesn't expect that to be a problem.

“So far, everything is encouraging. Very encouraging. Do we know stem cells are the answer? No. That's why it's called research,” said Feldman.

Also encouraging?

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Data from the first round of injections of 50,000 stem cells into a line of mice that have inherited genes for Alzheimer's disease.

"Look at this data," said Feldman, pointing to her computer screen. "I'm so geeked about this."

Two neurosurgeons on her team injected two groups of Alzheimer's mice, one group with a saline solution to serve as a control, the other with the stem cells. Both those groups and a group of healthy mice were then put through three tests of cognition, including one that required finding a platform hidden in a pool of water.

Plots of performance show that the Alzheimer's mice injected with cells performed the tests just as well as healthy mice. The Alzheimer's mice injected with saline solution flunked the tests.

"We've never seen data like this. It's just amazing. It's fabulous data that we're just getting ready to publish," said Feldman. "They're as normal as normal mice. They've essentially gone back to normal. And the effect was durable for the four months we tested them."

"I mean, you can tell looking at the mice which ones got stem cells. The ones who got saline solution just sat there in a cage. The stem-cell mice are all running around."

So far, the work on mice is unfunded, but with that kind of data, Feldman isn't concerned. "I'll get it funded," she said.

First, though, she awaits word from the **U.S. Food and Drug Administration** about which large mammal to use in the next set of Alzheimer's tests. For the ALS trials, the FDA had her use mini-pigs.

"If everything goes well, in a year from now we can be talking about clinical trials on humans," she said.