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FDA approves Phase II of stem cell trial for ALS

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For nearly two years, University of Michigan neurologist Eva Feldman, M.D., Ph.D. has led the nation's first clinical trial of stem cell injections in patients with the deadly degenerative disease known as amyotrophic lateral sclerosis, often called ALS or Lou Gehrig's disease.

Now, a new approval from the U.S. Food and Drug Administration paves the way for U-M to become the second site in the trial, pending approval of the U-M Institutional Review Board. To date, the first phase of the trial has taken place at Emory University, with Feldman serving as principal investigator.

The FDA approval of a Phase II trial was announced today by Neuralstem, the company whose product the trial is testing. The Phase II trial will continue to evaluate the safety of the stem cell injections, delivered directly into patients' spinal cords in escalating doses of up to 400,000 cells per injection, with a maximum of 40 injections. It will also assess any signs that the injections might be impacting patients' ALS symptoms or progression.

Feldman serves as an unpaid consultant to the company, and has led the analysis of results from the Phase I trial. In data presented last year, spinal cord injections of up to 100,000 cells were delivered safely and tolerated well—with possible signs that in one subgroup of participants, ALS progression may have been interrupted.

"In Phase II, we'll be injecting stem cells into the upper part of the spinal

cord, and our goal is to continue to assess whether this approach is safe, and to look at whether this approach offers some benefit to our patients. We are very pleased at the potential to bring this trial to the University of Michigan, where the initial research behind this technology was done—as well as having it continue at Emory," says Feldman, the Russell N. DeJong Professor of Neurology at the U-M Medical School, research director of U-M's ALS Clinic, and director of U-M's A. Alfred Taubman Medical Research Institute. The neurosurgeon for the trial is Parag Patil, M.D, Ph.D.

The approach uses injections of stem cells delivered during an operation performed by a neurosurgeon. The first phase of the trial involved 15 patients; specific plans for Phase II are still being made but information will be available at neuralstem.com.

If the U-M site team receives IRB approval to recruit local participants, more information will be available at uofmhealth.org. The study at U-M will be funded by the ALS Association, the National Institutes of Health and Neuralstem.

Provided by University of Michigan Health System

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