

New ALS treatment encourages hope

By Debbie Glover

St. Tammany News

Published on Wednesday, March 3, 2010 12:29 AM CST

[Print this story](#) | [Email this story](#) | [Post A Comment](#) |

“It was Aug. 27, 2009 — the day that changed our lives forever when he was diagnosed,” said Christine Jourdan, wife of 61-year old ALS patient and until recently, a firefighter, Dudley Jourdan of Covington.

Jourdan, his wife, daughter and granddaughter were at the unveiling of Dr. Gabriel Lasala’s ALS protocol announcement for the treatment of the disease, also known as Lou Gehrig’s disease. The announcement was made at a meeting of the ALS support group in Covington Monday night.

Thus far, Jourdan’s speech and some motor skills have become affected. But it is the future that frightens his family.

ALS, amyotrophic lateral sclerosis, is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. When the neurons die, the ability of the brain to initiate and control muscle movement is lost. In some cases, patients affected may become paralyzed and die.

Early symptoms can include muscle changes in speech, swallowing or While there is no cure, the drug riluzole progression of the disease.

Locally, a clinical protocol has been the FDA that may revolutionize treatment disease.

Lasala’s treatment protocol will use mesenchymal stem cells derived from the bone marrow. After the cells have number about 50 million, they will be the lumbar region of the spinal in a similar to a spinal tap.

Lasala then hopes the cells, which have renew themselves as well as the ability to different cells, will differentiate into oligodrocyte cells to facilitate anoxal glial function, secrete neurotransmitters the host and thereby slow the process.



Dudley Jourdan and his granddaughter Cara at the ALS support group meeting, hoping to be selected as a candidate for the Phase I protocol. (Staff Photo by Debbie Glover)

weakness, breathing slows

approved by of the

patient’s expanded to injected into method

the ability to become

growth or deficient in degenerative

“This is not a cure,” Lasala emphasized. “But it should slow progression of the disease and the patient may improve slightly.”

Lasala’s clinical trial is the only one of its kind in the world, with one protocol at Emory that will use allogenic (fetal) stem cells injected into the gray matter requiring five-10 injections and another study in Israel that has not been approved as of yet in that country.

Lasala’s procedure has been approved by the FDA for Phase I protocol for six patients. Once safety of the

treatment has been determined, Phase II will begin and more patients can be treated as part of the study.

In Phase I, all six patients will receive the stem cells and Lasala's treatment.

Phase II protocol patients, 30-60 of them, will be divided into two groups, with one group receiving placebo and the other group receiving the stem cell treatment, as with any scientific study. During Phase II, expanded access to the treatment will become available at a cost determined by the FDA. There is no cost to the patient when enrolled in the protocol.

Persons wishing to enter the Phase I protocol must meet the following inclusion criteria: be an adult male or female over the age of 18 years; have a good understanding of the protocol and be willing to participate; have a moderate to severe diagnosis of ALS; have a vital capacity of 50 percent predicted value; be diagnosed at least six months but no longer than 36 months; and have a hemocrit of 30 percent with a platelet count of at least 100,000 and an INR at or below 1.5.

In addition, protocol candidates can not have any of the following: a concurrent disease that affects the bone marrow; any concomitant medication that affects the bone marrow; any lymphoproliferative disease (lymphoma); riluzole with four weeks of study entry and at any time during the study; hemophiliacs or subjects with bleeding disorders; known hypersensitivity to fetal bovine serum; HIV infection; serum creatinine must be greater than 3.0 in subjects not on hemodialysis.

Also patients must not have a skin infection at the injection site or any systemic infection; no smokers; no active drug or alcohol addiction; no one who is pregnant or breast feeding; or no condition that the Principal Investigator considers would render the subject unfit for the study.

While most of us would not know the nature of some of the criteria, the terminology is all too familiar for those with the disease.

Lasala anticipates that the study will be proven safe and will move from Phase I to Phase II much faster than the 12 months the FDA is allowing him.

"This will halt the disease with a slight improvement to the patient, but is not a cure; the patient will not go back to normal. I don't think this will cure ALS with the technology currently available," said Lasala.

Lasala currently has seven protocols in progress, most dealing with heart function, and an eighth protocol is awaiting approval by the FDA that will concern spinal cord injury.

He fully expects this protocol to be on the "fast track" with the FDA and expanded access available soon. In expanded access, patients will be able to have the procedure done at a cost determined by the FDA. Lasala warns that stem cell treatment is expensive because of the technology involved. With pharmaceuticals (drug) research, investors often offset a lot of the cost because the end result will net a return on their investment.

Unlike drugs, stem cells do not sit on a shelf for years; they must be expensively maintained and preserved in labs.

Jourdan is hoping to be accepted into the first protocol. Diagnosed about six months, he is a good candidate. And he has an "ace up his sleeve" — his granddaughter Cara, 12, has become inspired by her grandfather and wants to become a microbiologist so she can find a cure for him and others.