MedicalXpress

Diaphragm pacing system receives FDA approval for use with ALS patients

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An electronic system that stimulates the nerve of the diaphragm muscles has received approval from the Food and Drug Administration (FDA) for use in patients with Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease. The system called NeuRx Diaphragm Pacing System (DPS) will help ALS patients breathe longer without the aid of a ventilator.

Dr. Raymond Onders, the surgeon at University Hospitals (UH) Case Medical Center who helped develop and test DPS and who lost his own sister to ALS this past year, began testing DPS 15 years ago on spinal cord injured patients such as the late actor Christopher Reeve. In 2004, this research expanded to included patients with ALS patients whose progressive muscle weakness leads to an inability to breathe without ventilator support.

"I lost my sister to this devastating disease during the FDA approval process," said Dr. Onders. "I also have seen the significant benefit diaphragm pacing can provide to patients. Diaphragm pacing has improved the breathing and quality of life of many of the patients I have treated. I am committed to searching for the cure for this disease but until then and with this approval we are now able to continue helping ALS patients until that cure is found," said Dr. Onders who is Director of Adult Minimally Invasive Surgery at UH Case Medical Center and who holds the Margaret and Walter Remen Chair in Surgical Innovation and is Professor of Surgery at Case Western Reserve University School of Medicine.

NeuRx DPS is made by Synapse Biomedical, Inc., a company co-founded by Dr. Onders.

Anthony R. Ignagni, Synapse's President and Chief Executive Officer, said, "We are very pleased the FDA approved this next indication for use of the NeuRx DPS to treat chronic hypoventation in ALS. In granting approval, it allows us to now offer individuals with ALS more time to be able to breathe with their own muscles."

The FDA granted a Humanitarian Device Exemption based on demonstration that NeuRx DPS could help ALS patients live longer, have better quality of life and sleep better than the current standard of care alone. These findings are the result of a multi-center clinical trial that enrolled 144 patients and treated 88 for chronic hypoventilation at UH Case Medical Center, Johns Hopkins, Stanford University and other major medical centers in the United States and France.

ALS is a rapidly progressing, incurable and fatal neuromuscular disease. As the phrenic nerve to the diaphragm muscles fails, patients have difficulty breathing. About 30,000 people in the United States live with ALS. More than 5,600 new cases are diagnosed each year, with an estimated subset of 3,300 with both chronic hypoventilation and intact phrenic nerves that could benefit from the NeuRx DPS® treatment.

In ALS, NeuRx DPS® is implanted through minimally invasive laparoscopic surgery and provides electrical stimulation to the diaphragm muscles. Repeated use of DPS conditions the diaphragm muscles, delaying respiratory failure and the need for tracheostomy and mechanical ventilation.

Provided by University Hospitals Case Medical Center