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Synapse Biomedical Receives FDA Approval for NeuRx Diaphragm Pacing System (DPS)[®] to Treat Amyotrophic Lateral Sclerosis (ALS)



CLEVELAND, Sept. 29, 2011 /PRNewswire/ -- [Synapse Biomedical, Inc.](#) announces that the U.S. Food and Drug Administration (FDA) has approved its [NeuRx Diaphragm Pacing System \(DPS\)[®]](#) for treating amyotrophic lateral sclerosis ([ALS](#)) patients who have stimulatable diaphragms and are experiencing chronic hypoventilation.

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(Fact sheets, patient testimonials, product videos and images: www.synapsebiomedical.com/news/media)

The FDA Humanitarian Device Exemption (HDE) marketing approval is based on demonstration that NeuRx DPS[®] could help ALS patients live longer and sleep better than the current standard of care, alone. These findings are the result of a multicenter clinical trial that enrolled 106 patients and treated 86 for chronic hypoventilation at:

1. University Hospitals Case Medical Center, Cleveland, Ohio
2. Johns Hopkins, Baltimore, Md.
3. Stanford University, Stanford, Calif.
4. Methodist Neurological Institute, Houston, Texas
5. Henry Ford Health System, Detroit, Mich.
6. Mayo Clinic, Jacksonville, Fla.
7. California Pacific Medical Center, San Francisco, Calif.
8. Groupe Hospitalier Pitie-Salpetriere, Paris, France

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

Amyotrophic lateral sclerosis (ALS), commonly referred to as Lou Gehrig's disease, is a rapidly progressing, incurable and fatal neuromuscular disease characterized by progressive muscle weakness that results in paralysis. As the phrenic nerve to the diaphragm muscles fails, patients lose the ability to breathe without ventilator support. Approximately 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 respiratory problems 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 NeuRx DPS[®] conditions the diaphragm muscles, delaying respiratory failure and the need for tracheostomy and mechanical ventilation.

Fifteen years ago, Dr. Raymond Onders, co-founder of Synapse Biomedical, began clinical research at University Hospitals Case Medical Center to help spinal cord injured patients breathe, including the late actor Christopher Reeve. In 2004, this research expanded to include patients with ALS. Presently, Dr. Onders holds the Margaret and Walter Remen Chair in Surgical Innovation and is a professor of Surgery at Case Western Reserve University School of Medicine. ALS has affected Dr. Onders and his family personally. "I lost my sister to this devastating disease this past year. I have also seen the significant benefit diaphragm pacing can provide to patients. Diaphragm pacing has improved the breathing and longevity of many of the patients I have treated. As medical researchers, we are committed to searching for the cure for ALS but until then, this approval allows us to help these patients," said Dr. Onders.

"We plan to work closely with the Medical Directors at the ALS Association Certified Centers(sm) (www.alsa.org) and MDA/ALS Centers (www.als-mda.org/clinics) to establish a local treatment option. To support immediate treatment requests, we will be working initially with our previous clinical trial center investigators (www.synapsebiomedical.com/als/usneurx-centers.shtml)," said Steven Annunziato, Synapse Biomedical SVP Marketing and Sales.

"This is excellent news, indeed, for ALS patients, their caregivers, and for health care providers in general who treat ALS patients," said University of Vermont ALS Association Certified Center Medical Director Rup Tandan, MD, FRCP. "The availability of the NeuRx DPS device to appropriate ALS patients is a major advance in the treatment of the disease that will enhance survival and quality of life in ALS patients. The planned partnership with certified ALS centers across the United States to make the device available to patients, and to provide adequate training to interested sites, will capitalize on the existing network of centers to enhance the quality of care offered to patients. Educational opportunities for the ALS community will also be significantly bolstered by this partnership between Synapse Biomedical and the certified ALS centers. I will look forward to our center's participation in these efforts to positively influence the lives of ALS patients and their caregivers.

"The ALS Association is proud to support The ALS Association Certified Centers(sm) and their participation in clinical trials," said ALS Association President and CEO Jane Gilbert. "We are excited about the potential this therapy offers to help improved quality of life options available for those living with ALS."

"Approval of NeuRx DPS, with its potential to improve both survival and quality of life, is great news for the ALS community," said Valerie Cwik, M.D., MDA's Medical Director and Executive Vice President – Research. "MDA is very pleased that NeuRx DPS will now be a treatment option for individuals with ALS across the United States."

"I applaud the FDA's decision to approve the diaphragm pacer so all ALS patients can have access to it. Getting this device was one of the best decisions I've made since my diagnosis. It helped me delay the need for a tracheostomy until this summer, more than six years after my diagnosis. The operation was simple, and I had no trouble with the pacer since it was installed. Most people with ALS ultimately will face a decision about going on a vent. The pacer will help extend that decision while we help find a cure," said Augie Nieto, Co-Chair of MDA's ALS Division, and Chief Inspiration Officer of Augie's Quest

NeuRx DPS® received CE Mark #518356 on November 20, 2007, and is approved for treating patients with diaphragm dysfunction in the European Union. Centers outside the United States include Charite - Universitätsmedizin in Berlin Germany, Medizinische Hochschule in Hannover Germany, Royal Hallamshire Hospital in Sheffield UK, University Hospital Gasthuisberg in Leuven Belgium, UMCG Groningen in the Netherlands and the Group Hospitalier Pitie-Salpetriere in Paris, France where ALS was first classically described by Jean-Martin Charcot. (www.synapsebiomedical.com/eu/euneurx-centers.shtml)

NeuRx DPS® also is approved in the United States under an HDE for spinal cord injury (SCI) patients, 18 years or older who have stimlatable diaphragms but lack control of their diaphragms. Today, 44 U.S. centers are approved for SCI treatment and are listed at www.synapsebiomedical.com/products/us_sci.shtml.

Technical and Procedure Description

NeuRx DPS® is a four-channel, battery-powered external pulse generator (EPG) with electrodes that are implanted through minimally invasive laparoscopic surgery. The device provides electrical stimulation to the muscle and nerves of the diaphragm.

During the procedure, a surgeon creates four dime-sized holes in the abdomen and inserts a laparoscope so the diaphragm muscle can be seen. The surgeon then places small electrodes in the diaphragm. The electrodes are attached to the EPG, which stimulates the diaphragm, causing a contraction of muscle. The ALS surgery can be done on an outpatient basis. Post-operatively, the EPG is programmed, and the patients and caregivers are trained on the use of NeuRx DPS®. The stimulation is then used to condition the diaphragm, enabling the patient to breathe longer without the need for tracheostomy ventilation.

About Synapse Biomedical & NeuRx DPS®

Synapse Biomedical is headquartered in Oberlin, Ohio (30 miles west of Cleveland) and was founded in 2002 to commercialize the NeuRx® platform for treating a number of severe breathing problems with minimally invasive neurostimulation technology.

For more information on Synapse Biomedical, fact sheets, patient testimonials, product videos and high-resolution images, and the surgical procedure please visit: www.synapsebiomedical.com/news/media.

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