Synapse Biomedical Receives FDA Humanitarian Use Device Designation for Amyotrophic Lateral Sclerosis (ALS)

CLEVELAND, Oct. 8 /PRNewswire/ -- **Synapse Biomedical Inc**. announces today that they have received the U.S. Food and Drug Administration (FDA) designation of the NeuRx Diaphragm Pacing System (DPS)™ as a Humanitarian Use Device (HUD) for amyotrophic lateral sclerosis (ALS) patients with a stimulatable diaphragm who are experiencing chronic hypoventilation and has now submitted for Humanitarian Device Exemption (HDE) approval.

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The HUD designation establishes that the NeuRx DPS™ is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The HUD designation is necessary to apply for HDE market approval. With our submission of the HDE application on October 8, 2010, the FDA will now review the Synapse HDE application to determine whether NeuRx DPS™ is safe and has probable benefit for ALS patients who meet the HUD population criteria. "We anticipate that the HDE initial review will take 75 days although FDA questions can result in additional review cycles," stated Mike Fritz, Synapse VP Clinical & Regulatory Affairs.

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. Voluntary muscle control is lost as the nerves die. As a result, patients lose the ability to breathe, without ventilator support, as the phrenic nerve to their diaphragm muscles fail. Approximately 30,000 people in the United States live with ALS. More than 5,000 new cases are diagnosed each year, with an estimated subset of 3,300 with both chronic hypoventilation and intact phrenic nerves that could potentially benefit from treatment with the NeuRx DPS™.

In ALS, the NeuRx DPS™ provides electrical stimulation to the diaphragm muscles and continues to exercise the muscles, in an attempt to delay diaphragm atrophy and the need for invasive mechanical ventilation. NeuRx DPS™ stimulates the diaphragm, causing a contraction that mimics natural breathing.

"In our efforts to help people with this devastating disease, we are using and focusing every available resource to help advance the availability of the NeuRx treatment. Having obtained HUD designation and filed our HDE application for ALS, we will now seek Continued Access approval for our clinical trial centers," said Anthony R. Ignagni, Synapse President and Chief Executive Officer. Continued Access (CA) is an Office of Device Evaluation (ODE) policy that permits sponsors of clinical investigations to continue to enroll subjects while a marketing application is being reviewed by the ODE. The ODE grants CA based on a public health need for the device or if there is preliminary evidence the device is likely to be effective and no significant safety concerns have been identified for the proposed indication.

In the United States, the NeuRx DPS™ received investigational device status in October 2005 for use in a clinical trial for ALS. The following clinical sites were approved to participate in NeuRx DPS™ clinical testing for ALS:

- University Hospitals Case Medical Center, Cleveland, Ohio
- Johns Hopkins, Baltimore, Md.
- Stanford University, Stanford, Calif.
- Methodist Neurological Institute, Houston, Texas
- Henry Ford Health System, Detroit, Mich.
- Mayo Clinic, Jacksonville, Fla.
- California Pacific Medical Center, San Francisco, Calif.
- Mount Sinai Medical Center, New York, N.Y.

The NeuRx DPS™ received CE Mark (CE Registration #518356) on November 20, 2007, as well as TGA approval in Australia on January 20th, 2009 and is approved for treating patients with diaphragm dysfunction in the European Union. Several SCI patients have been implanted at prominent centers across Europe, Australia and the Middle East. ALS patients have been implanted successfully as well at leading centers, including Groupe Hospitalier Pitie-Salpetriere (Paris, France), Charite Universitatsmedizin Hospital (Berlin, GMBH), Royal Hallamshire Hospital (Sheffield, UK), University Medical Center (Groningen, Netherlands) and Landspitali - University Hospital (Reykjavik, Iceland).

The NeuRx DPS™ is currently approved in the United States under an HDE for spinal cord injury (SCI) patients, 18 years or older with stimulatable diaphragms but lack control of their diaphragms. Today 34 centers in the United States are approved for SCI treatment and are listed at www.synapsebiomedical.com/products/us_sci.shtml

Currently, the top three treatment centers worldwide are:

- University Hospitals Case Medical Center, Cleveland, Ohio
- Groupe Hospitalier Pitie-Salpetriere, Paris, France
- Piedmont Hospital, Atlanta, Georgia

Technical and Procedure Description

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

During the procedure, a surgeon creates four dime-size holes in the abdominal region 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 that stimulates and causes a contraction of the diaphragm. The ALS surgery is typically done on an outpatient basis.

Post-operatively, the EPG is programmed and the patients and caregivers are trained on the use of the NeuRx DPS™.

About Synapse Biomedical & NeuRx DPS™

Synapse Biomedical, headquartered in Oberlin, Ohio, 30 miles west of Cleveland, was founded in 2002 to commercialize the NeuRx™ platform for treating a number of respiratory insufficiency conditions with minimally invasive neurostimulation technology.

For more information about Synapse Biomedical including 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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