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Synapse Biomedical Receives FDA Approval of NeuRx Diaphragm Pacing System (DPS)[™] For Spinal Cord Injury Breathing Applications

NeuRx DPS[™] Allows Patients To Breathe Without Ventilator Clinical Trials Also Underway For ALS Patients

Cleveland, OH (JUNE 17, 2008) – Synapse Biomedical Inc. (www.synapsebiomedical.com) announced today it has received approval from the U.S. Food and Drug Administration (FDA) for its NeuRx DPS[™] for ventilator-dependent Spinal Cord Injury (SCI) patients who lack voluntary control of their diaphragms. With the FDA's approval, SCI patients and their caregivers throughout the U.S. can now access this technology that was previously only available to clinical trial participants.

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

The device implanted through minimally invasive laparoscopic surgery, provides electrical stimulation to muscle and nerves that run through the diaphragm. When stimulated by the NeuRx DPS[™], the diaphragm contracts, mimicking natural breathing, and allows air to fill the upper and lower parts of the lungs rather than forcing air in with a mechanical ventilator.

The NeuRx DPS[™] received the CE Mark (CE Registration #518356) on November 20, 2007 and is approved for treating patients with diaphragm dysfunction in the European Union. Seven successful implants have occurred at leading European hospitals including: Charite – Univeritatsmedizin (Berlin); Groupe Hospitalier Pitie-Salpetrier (Paris) and Institut GUTTMANN – Hospital De Neuro Rehabilitacio (Barcelona) since that date.

The FDA decision was completed after clinical testing, which began with clinical trials starting in 2000 under Investigational Device Exemption #G920162.

The FDA approval is based on 50 patients implanted with the device in clinical trials at hospitals in the U.S. and Canada – University Hospitals Case Medical Center, Ohio; Shepherd Center, Atlanta, Ga.; Methodist, Houston, Texas; and Vancouver General Hospital, Vancouver. All of the implanting surgeons were trained in the device under the direction of Dr. Raymond Onders, director of minimally invasive surgery at University Hospitals, Cleveland, and a founder, board member and shareholder of Synapse Biomedical. Dr. Onders will continue to proctor initial surgeries as regional trauma centers begin to offer the NeuRx DPS[™] to spinal cord patients.

“We are pleased the FDA has given approval to NeuRx DPS[™] so we can now offer individuals throughout the United States the ability to breathe on their own once again,” said Anthony R. Ignagni, Synapse President and Chief Executive Officer. “The national launch of the NeuRx DPS[™] represents Synapse’s first step in applying its NeuRx[™] neurostimulation platform to U.S. patients with chronic and acute respiratory insufficiency which has the promise of reducing healthcare costs while improving outcomes.”

Technical description

In the clinical trial, NeuRx DPS™ provided 98% of SCI patients who had been dependent on mechanical ventilation via a tracheostomy with an alternative that allowed them to breathe normally and live more active lives. To date, over 50% were able to be completely eliminate their need for mechanical ventilation.

Patients may be able to transfer from ventilator wards to home or assisted living, and even travel. Speech patterns, often laborious and strained in ventilator-dependent patients, return to normal. The senses of taste and smell, severely diminished in ventilator-dependent patients, return.

Controlled through a four-channel battery-powered external pulse generator, the NeuRx DPS™ eliminates the need for a source of electricity and the concern for power outages. Patients and caregivers are easily trained in the use of the NeuRx DPS™ reducing the need for external medical supervision. Elimination and reduction of the use of a mechanical ventilator also greatly reduces the patient's risk of a serious complication: Ventilator Acquired Pneumonia (VAP). In a peer review 2007 report in Physical Medicine and Rehabilitation Clinical of North America by Stephen P. Burns MD, the incidence of SCI pneumonia for initial admitted patients was reported to be as high as 50 percent. The associated mortality from pneumonia was reported as 28% in the first year.

Background

The NeuRx DPS™ was developed over the course of 20 years through a joint effort of physicians and engineers at several institutions, including University Hospitals Case Medical Center, Case Western Reserve University (a shareholder of Synapse Biomedical) and the Veterans Administration (VA) Medical Center. Funding assistance was provided by the Food and Drug Administration, U.S. Surgical Corporation (a Division of Covidian), University Hospitals Case Medical Center, the VA, and the National Center for Research Resources of the National Institutes of Health. Synapse Biomedical, headquartered in Oberlin, OH., was founded in 2002 to bring its NeuRx™ platform of Diaphragm Pacing technologies to market. These technology platforms resolve a number of respiratory clinical needs and create a neurostimulation market segment for these treatments. Clinical studies and research for other applications are ongoing.

Candidates for this U.S. approval of the NeuRx DPS™ are:

- Patients with stable, high level spinal cord injury with stimlatable diaphragms, but lack control of their diaphragm, resulting in the need for mechanical ventilation
- For use only in patients 18 years of age or older"

The majority of eligible patients have suffered injury through motor vehicle accidents and sports injuries. An estimated 3,700 individuals in the U.S. live with high (C1-C3) SCI injuries that require tracheostomy and mechanical ventilation. Approximately 500 new cases occur each year.

Surgical procedure

Using a form of minimally invasive laparoscopic surgery, a surgeon creates four dime-size holes in the abdominal region and inserts a laparoscope so that the diaphragm muscle can be seen. The surgeon then places small electrodes in the diaphragm. The electrodes are attached through wires under the skin to a small external battery-powered pulse generator that stimulates contraction of the diaphragm muscle which allows the patient to breathe.

The surgery is done on an outpatient basis, with a short rehabilitation period. The patient then has the NeuRx DPS™ programmed to allow an effective and comfortable breath. Because of the patient's injury, the diaphragm is weak and at first the patient can only breathe with NeuRx DPS™ for a short period of time. The patient has to condition and strengthen the diaphragm to allow increasing amount of time off the ventilator on an almost daily basis. Many patients are able to free themselves completely from the ventilator. For more information on the surgical procedure, please visit www.synapsebiomedical.com/news/media.

Where Patients Can Go For Help

Patients and caregivers who want to find a doctor who can evaluate their case for possible treatment with the NeuRx DPS™ should visit www.synapsebiomedical.com for more information. To read the stories of successfully implanted patients, visit <http://www.synapsebiomedical.com/news/success/>.

ALS Clinical Trials Also Underway

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. All voluntary control muscles are weakened, and, as a result, diaphragm muscles fail. Patients lose the ability to breathe without ventilator support.

Approximately 30,000 people in the U.S. live with ALS. Over 5,000 new cases are diagnosed each year. It is estimated that fewer than five percent of ALS patients choose to be placed on ventilators.

The NeuRx DPS™ received IDE #G040142 status in October 2005 for use in clinical trials on ALS patients. The pilot study accomplished in 16 patients was initiated in January 2005. It demonstrated the feasibility of the NeuRx DPS™ to slow the decline of a patient's respiratory function as measured by Forced Vital Capacity and as a result delays the onset of respiratory failure.

The following medical sites are participating 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, NY, N.Y.

Clinical trials for use of the NeuRx DPS™ for ALS are also underway in Europe. For more information on ALS, please visit the Synapse newsroom at www.synapsebiomedical.com/news/media.

About Synapse Biomedical

Founded in 2002, Synapse Biomedical's mission is to commercialize our life-transforming neurostimulation platform used to treat people with respiratory insufficiency. Synapse is based in Oberlin, Ohio, approximately 30 miles west of Cleveland. For more information, including fact sheets, frequently asked questions, high-resolution images and broadcast quality video, please visit www.synapsebiomedical.com/news/media.

About University Hospitals Case Medical Center

University Hospitals Case Medical Center is a community-based health care system which serves patients at more than 150 locations throughout Northern Ohio, including seven wholly owned and four affiliated hospitals.

Committed to advanced care and advanced caring, UH encompasses the region's largest network of primary care physicians, outpatient centers and hospitals. The network also offers specialty care physicians to treat almost every disease and condition, skilled nursing, elder health, rehabilitation and home care services, and occupational health and wellness.

University Hospitals is the second largest private sector employer in Northeast Ohio and is within the top five largest private sector employers in the state of Ohio.