NeuroMetrix Receives 510(k) Clearance for SENSUS™ Pain Management Device

The Associated Press

WALTHAM, Mass.--(BUSINESS WIRE)--Aug 6, 2012--NeuroMetrix, Inc. (Nasdaq: NURO), www.neurometrix.com, a medical device company focused on the diagnosis and treatment of the neurological complications of diabetes, announced that it has received 510(k) clearance for its SENSUS Pain Management device from the U.S. Food and Drug Administration (FDA). This regulatory determination by the FDA gives NeuroMetrix clearance to market the SENSUS device in the U.S. market. The device is intended for use as a transcutaneous electrical nerve stimulator for the symptomatic relief and management of chronic intractable pain.

“This product has attracted attention among health care providers because of its potential benefit to patients suffering from chronic pain,” said Shai N. Gozani M.D., Ph.D., President and Chief Executive Officer of NeuroMetrix. “FDA clearance keeps us on track to launch the SENSUS Pain Management System in the fourth quarter of 2012. We are particularly enthusiastic about adoption of the device by diabetes focused clinicians because a number of recent systematic literature reviews and meta-analyses have concluded that transcutaneous electrical nerve stimulation may be an effective and safe treatment for painful diabetic neuropathy.” About NeuroMetrix NeuroMetrix is an innovative medical device company that develops and markets home use and point-of-care devices, associated consumables, and support software for the treatment and management of diabetes and its complications. The company is focused on nerve related complications of diabetes, called diabetic neuropathies, which affect over 50% of people with diabetes. If left untreated, diabetic neuropathies trigger foot ulcers that may require amputation, cause disabling chronic pain, and increase the risk of falling in the elderly. The annual cost of diabetic neuropathies has been estimated at $14 billion in the United States. The company’s products are used by physicians and other clinicians, in retail health settings such as pharmacies, and by managed care organizations to optimize patient care and reduce healthcare costs. The company markets the NC-stat ® DPNCheck ™ device, which is a rapid, accurate, and quantitative point-of-care test for diabetic neuropathy. This product is used to detect diabetic neuropathy at an early stage and to guide treatment. The company is in late stage development of SENSUS ™, a pain management device. The company has additional therapeutic products in its pipeline. For more information, please visit http://www.neurometrix.com.

CONTACT: NeuroMetrix, Inc.

Thomas T. Higgins, 781-314-2761 SVP and Chief Financial Officer
neurometrix.ir@neurometrix.com KEYWORD: UNITED STATES NORTH AMERICA MASSACHUSETTS INDUSTRY KEYWORD: HEALTH BIOTECHNOLOGY MEDICAL

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