

NeuroMetrix Completes 510(k) Clearance Process for SENSUS™ Pain Management System

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 29, 2012-- NeuroMetrix, Inc. (Nasdaq: NURO), www.neurometrix.com, a medical device company focused on the diagnosis and treatment of the neurological complications of diabetes, reported that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the disposable electrode that is used in conjunction with its SENSUS device. This regulatory determination by the FDA gives NeuroMetrix clearance to market the SENSUS Pain Management System in the U.S. market.

The SENSUS device is a transcutaneous electrical nerve stimulator intended for the symptomatic relief and management of chronic intractable pain in the lower leg and foot. It is a light weight, low profile device worn on the upper calf and activated by the press of a single button. It can be placed in seconds and may be worn under clothing.

"FDA clearance of the SENSUS electrode represents the last step in the regulatory pathway for the SENSUS Pain Management System," said Shai N. Gozani M.D., Ph.D., President and Chief Executive Officer of NeuroMetrix. "We believe that physicians treating patients with painful diabetic neuropathy, a severe and debilitating form of chronic pain, will find SENSUS to be a useful therapeutic option. We intend to initiate the commercial launch for SENSUS before the end of the year, in line with the goal that we set over a year ago."

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[®] DPNCheckTM 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 has also begun to market the SENSUS Pain Management System for treating chronic pain, focusing on physicians managing patients with painful diabetic neuropathy. The company has additional therapeutic products in its pipeline. For more information, please visit http://www.neurometrix.com.

Source: NeuroMetrix, Inc.

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