ATI Neurostimulation System Shown to be Highly Effective in Treating Cluster Headache

The Associated Press

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Feb 5, 2013--Autonomic Technologies, Inc. (ATI), the developer of the ATI Neurostimulation System designed for the treatment of severe headaches, today announced results of their clinical study in cluster headache, now published online.[1] The robust, multi-centre, randomized, placebo-controlled clinical study is the largest study performed with a medical device for cluster headache.

The study showed that the ATI Neurostimulation System demonstrated clinical effectiveness in treating cluster headache, and provided significant improvement in patient quality of life and headache disability. The results were statistically significant:

- Pain relief at 15 minutes was achieved in 67.1% of treated attacks compared to 7.4% of sham treated attacks ($p<0.0001$)
- Pain freedom at 15 minutes was achieved in 34.1% of treated attacks compared to 1.5% of sham treated attacks ($p<0.0001$)
- The average number of cluster attacks per week was reduced by 31% ($p=0.005$), and 43% of patients experienced an average reduction of 88% in the number of attacks suffered 64% of patients experienced clinically significant improvement in headache disability (HIT-6)
- 75% of patients experienced clinically significant improvements in quality of life (SF-36v2 physical and/or mental component scores) Acute rescue medications were used in only 31.0% of treated attacks compared to 77.4% of sham treated attacks ($p<0.0001$), a reduction of 60%
- The ATI Neurostimulation System was well tolerated, and side effects were comparable to other similar surgical procedures and tended to be transient

Cluster headache is one of the most painful types of headache. Patients may experience multiple attacks daily or almost daily, associated with excruciating pain typically in the area of one eye. Each attack can last between 15 minutes and three hours.[1] Often called 'suicide headaches' because of their severity,[2] it is estimated that over 600,000 people across Europe suffer from cluster headaches.[3,4]

"Cluster headaches cause so much disability that patients are often unable to function normally," said Prof. Dr. Jean Schoenen, Full Professor of Functional Neuroanatomy and coordinator of the Headache Research Unit at University of Liege in Liege, Belgium. "Current preventive treatments are often ineffective, and in many patients acute and preventive treatments may not be tolerated or are contraindicated. This new and innovative therapy offers a way for a significant number of patients to control the debilitating pain of cluster headache.”

The ATI Neurostimulation System is a novel, rechargeable system, with an implantable neurostimulator that is smaller than an almond. Designed for the treatment of severe headache, the neurostimulator is activated using an external remote controller (similar in size to a smart phone), allowing patients to deliver as-needed stimulation to relieve the attack. After a headache is treated, the remote controller is simply moved away from the cheek, turning off stimulation therapy.

“The ATI Neurostimulation System is well tolerated and can be used as often as needed, without daily limitations or stimulation-induced side effects”, said Prof. Dr. Rigmor Hoejland Jensen, Director of the Danish Headache Center at Glostrup Hospital in Denmark. “Based on the results of the study, this new treatment option offers a significant improvement in quality of life to the majority of patients.” The ATI Neurostimulation System works by stimulating the sphenopalatine ganglion (SPG), a nerve bundle deep in the face that for years has been shown to play an important role in cluster headache.

“For years clinicians have targeted the SPG to relieve severe headache, primarily by applying anesthetics and other agents to achieve a nerve block,” said Prof. Dr. Arne May, Neuroscientist at the University Hospital Hamburg-Eppendorf and First Vice President of the German Migraine and Headache Society. “This study provides clear evidence that SPG stimulation is a feasible and effective therapy for the treatment of cluster headache.” "We are very pleased with the positive results of the clinical study," said Ben Pless, President and Chief Executive Officer of Autonomic Technologies. "We are delighted to start making the ATI Neurostimulation System available to cluster headache patients in Europe so that they may control their painful attacks." The ATI Neurostimulation System is CE marked for the treatment of cluster headache. Initial centres in Germany and Denmark are now treating suitable cluster headache patients with the ATI Neurostimulation System. ATI plans to begin an investigational study of the device in the US in the near future. Patients who wish to explore this new therapy should ask their doctor for a referral to a headache specialist or neurologist who is qualified to evaluate, diagnose and properly manage cluster headache.

About cluster headaches
Cluster headache is a highly disabling chronic neurological condition characterized by intense stabbing pain in the area of one eye, often accompanied by swelling, tears and nasal congestion. The pain inflicted by the condition is recognized as among the most severe known to humans. Sufferers can have headache attacks multiple times per day, each lasting 15 to minutes to three hours. Approximately 1.2 in 1,000 people suffer from cluster headaches.

The socioeconomic burden of cluster headache on the individual and society is high due to direct costs of healthcare services and indirect costs of lost work days and decreased work efficacy. A Danish report showed that 43.5% of cluster patients had seen specialists, approximately 30% had missed work, and 78% reported restrictions in daily living.[5] A recent German study showed that a single chronic cluster headache patient could cost the healthcare system over €21,000 per year.[6] There is no cure for the condition. Current treatments to relieve symptoms include

preventive and acute abortive drugs, including injectable medications and inhaled oxygen. As some patients are not candidates for these medications, and others may experience significant side effects or have cardiovascular risk factors that place them at risk for taking these medications, there is a considerable need for a new treatment option.

About Autonomic Technologies, Inc.
Autonomic Technologies, Inc. (ATI) is a medical device company focused on the development and commercialization of innovative therapies for the treatment of severe headache. The company's initial product, the ATI Neurostimulation System, is approved in Europe for the treatment of cluster headache and is currently being investigated in a multi-center, randomized study for the treatment of high frequency, high disability migraine.

The ATI Neurostimulation System was voted #2 among the Cleveland Clinic's top 10 medical innovations for 2013, and Autonomic Technologies was named one of 'FierceMedicalDevices' Fierce 15 most promising privately held medical device and diagnostics companies in the world.

ATI is located in the San Francisco Bay Area and is backed by blue chip investors Kleiner Perkins Caufield and Byers, InterWest Partners, Versant Ventures, Novartis Ventures, Aberdare Ventures, and the Cleveland Clinic.

For more information on ATI, or to learn more about the ATI Neurostimulation System and the hospitals that are currently offering this therapy to patients with cluster headache, please visit www.ati-spg.com [1].

References:
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[1] http://www.ati-spg.com
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