



## **MONTERIS MEDICAL RECEIVES IDE APPROVAL FROM FDA TO EVALUATE NEUROBLATE® IN PATIENTS WITH MEDICALLY REFRACTORY EPILEPSY**

***Laser ablation is being studied to determine its effect on U.S. epilepsy patients who do not respond to drug treatment<sup>1</sup>***

PLYMOUTH, Minn. – April 7, 2016 – Monteris Medical announced the U.S. Food and Drug Administration (FDA) has approved the company’s Investigational Device Exemption (IDE) to evaluate its NeuroBlate® System in medically refractory epilepsy. With this approval, Monteris will initiate the Feasibility Study on Laser Interstitial Thermal Ablation for the Treatment of Medically Refractory Epilepsy (FLARE). This multicenter, open-label prospective study is expected to enroll up to 45 subjects at as many as eight clinical sites in the U.S., with the goal of evaluating approximately 30 patients using laser interstitial thermal therapy (LITT) for neurosurgical applications.

Since obtaining initial FDA clearance in 2013, the NeuroBlate System has been used by surgeons to destroy and coagulate neurosurgical soft tissue lesions

The Centers for Disease Control and Prevention estimate that there are about 2.9 million people in the U.S. with active epilepsy and that about one third of these patients continue to experience seizures despite treatment with one or more anti-epileptic drugs.<sup>1</sup>

“Many refractory epilepsy patients in the U.S. are eligible for resection surgery treatment, but the vast majority of patients and their doctors choose not to undertake such an invasive procedure due to the underlying risks associated with traditional open brain surgery,” said Dennis Spencer, M.D., Chair of the Department of Neurosurgery at Yale University School of Medicine and Principal Investigator of the study. “The FLARE study will help to determine whether patients may benefit from a minimally invasive procedure, such as LITT. FLARE is designed to provide important insight into the safety and efficacy of this approach and its potential impact on neurocognition and seizures. This study is an important step forward in evaluating a new modality designed for medically refractory epilepsy.”

FLARE is designed to evaluate the performance of LITT using the Monteris NeuroBlate System for the treatment of drug-refractory medial temporal lobe epilepsy in appropriate candidates. The primary endpoint of the study is to characterize the safety of laser ablation surgery with the NeuroBlate System in this patient population, including evaluation of adverse events and neuropsychological changes. Seizure outcome and quality of life will be evaluated as secondary endpoints. Patients enrolled in the study will undergo laser ablation surgery and will then be followed for 24 months. Monteris Medical expects to initiate FLARE in the second half of 2016 and estimates that it will take approximately 3.5 years to complete the study.

“Refractory epilepsy represents a significant unmet medical need. The FLARE study will help increase our understanding of the potential benefit the NeuroBlate System may have on the quality of life of patients living with this serious and debilitating disease,” said Daryle Petersen, Vice President, Clinical Affairs at Monteris Medical.



## About Monteris®

Monteris® Medical is a privately held company developing innovative MRI-guided, laser-based brain lesion therapy. Monteris Medical markets the NeuroBlate® System, a neurosurgical ablation device providing controlled therapy for brain lesions. The company also offers the Monteris Mini-Bolt, the only cranial bolt system that enables a robotic interface for protected and precise therapy delivery, as well as the AtamA™ Stabilization System for MRI-guided neurosurgical procedures requiring head fixation.

For more information on Monteris Medical please visit [www.monteris.com](http://www.monteris.com).

# # #

Media Contacts: Danielle Lewis or Erich Sandoval  
LAZAR PARTNERS LTD. for Monteris Medical  
[dlewis@lazarpartners.com](mailto:dlewis@lazarpartners.com) or [esandoval@lazarpartners.com](mailto:esandoval@lazarpartners.com)  
212-843-0211 or 917-497-2867

---

<sup>1</sup> Centers for Disease Control and Prevention. Epilepsy Fast Facts. Available at <http://www.cdc.gov/epilepsy/basics/fast-facts.htm>. Accessed 3/11/16.