



## **MONTERIS MEDICAL RECEIVES IDE APPROVAL FROM FDA TO EVALUATE NEUROBLATE® IN PATIENTS NEWLY DIAGNOSED WITH GLIOBLASTOMA MULTIFORME**

### ***Third IDE Study Supports Potential Expanded Use of Laser Ablation Technology***

PLYMOUTH, Minn. – September 1, 2016 – Monteris Medical announced the U.S. Food and Drug Administration (FDA) has approved an Investigational Device Exemption (IDE) to evaluate the NeuroBlate® System in patients newly diagnosed with glioblastoma multiforme (GBM). With this approval, Monteris will initiate the Feasibility Study on Laser Interstitial Thermal Ablation for the Treatment of Newly Diagnosed GBM (FLAG), an open-label, prospective study that will be conducted in five sites in the United States.

The NeuroBlate System, a type of MRI-guided laser interstitial thermal therapy (LITT), is used by surgeons to destroy and coagulate soft tissue lesions in the brain. Monteris previously conducted an IDE approved study to evaluate the NeuroBlate System in patients with recurrent GBM and recently announced an additional IDE approval to evaluate the System in patients with medically refractory epilepsy.

GBM is the most common and deadliest type of primary brain tumor. It occurs most commonly in adults between the ages of 45 and 70 years and it accounts for 52 percent of primary brain tumors, and about 17 percent of all brain tumors (including primary and metastatic).<sup>1</sup> The 5-year relative survival rate for GBM ranges from 4-17 percent and decreases with age.<sup>2</sup>

“Glioblastoma multiforme continues to be one of the most lethal cancers, and new approaches for managing this disease are urgently needed,” said Eric C. Leuthardt, M.D., Professor of Neurological Surgery at Barnes-Jewish Hospital and Director of the Center for Innovation in Neuroscience and Technology, and the Brain Laser Center at Washington University School of Medicine. “Preliminary data suggest that LITT may have potential in newly diagnosed GBM cases, and the FLAG study will further our understanding of its potential in improving the care and outcomes for patients. Additionally, we anticipate LITT’s minimally invasive approach may have benefits over open craniotomy for this population.”

“Although complete tumor resection in GBM is associated with improved survival, traditional open surgery is not optimal for patients with difficult to access deep seated lesions, and it also carries an increased risk of damage to adjacent healthy tissue,” said Kris Smith, M.D., practicing neurosurgeon at the Barrow Neurological Institute in Phoenix. “Data from a preliminary first in human study evaluating laser thermotherapy to treat recurrent GBM demonstrated clinical potential and we expect ongoing research will help us better understand how patients with newly diagnosed GBM respond to this type of intervention.”

FLAG is designed to characterize the safety, feasibility and effectiveness of the NeuroBlate System in combination with standard of care radiation and chemotherapy in patients with newly diagnosed GBM. The study will enroll participants for whom a complete surgical resection is unsafe due to location, shape or size of the tumor. Overall survival, progression-free survival, patient quality of life and healthcare utilization will be assessed during the trial in 30 patients



followed for up to 12 months after the procedure and subsequent radiation and chemotherapy. Monteris Medical expects to initiate FLAG in the fourth quarter of 2016.

“Monteris Medical is committed to addressing unmet medical needs by evaluating new options for patients with severe neurological disorders, and the IDE process enables us to do so in a carefully regulated, clinically rigorous environment,” said Daryle Petersen, Vice President, Clinical Affairs at Monteris Medical. “We are optimistic that results from the FLAG study will expand our knowledge of LITT in this patient population.”

### **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).

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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

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<sup>1</sup> American Association of Neurological Surgeons. Glioblastoma Multiforme. Available at: <http://www.aans.org/patient%20information/conditions%20and%20treatments/glioblastoma%20multiforme.aspx>. Accessed 8/9/16.

<sup>2</sup> American Cancer Society. Survival Rates for Selected Adult Brain and Spinal Cord Tumors. Available at: <http://www.cancer.org/cancer/braincnstumorsinadults/detailedguide/brain-and-spinal-cord-tumors-in-adults-survival-rates>. Accessed 8/9/16