MONTERIS MEDICAL ANNOUNCES DATA REINFORCING CLINICAL EFFICACY OF NEUROBLATE® LASER ABLATION IN PATIENTS WITH BRAIN LESIONS

Results and case study findings presented at the 2015 Congress of Neurological Surgeons (CNS) Annual Scientific Meeting

NEW ORLEANS – September 29, 2015 – Monteris Medical today announced recent data demonstrating that newly diagnosed brain tumor patients undergoing procedures with the NeuroBlate® System, a minimally invasive robotic laser thermotherapy tool, experienced improved outcomes. These findings, along with a separate case study presentation highlighting the first successful ablation of the hippocampus and amygdala using a directional laser, were presented during the 2015 Congress of Neurological Surgeons (CNS) Annual Scientific Meeting in New Orleans.

“To date, limited data have been available on brain tumor patients that received MRI-guided laser ablation,” said Alireza Mohammadi, M.D., a neurosurgeon from a prestigious medical center in Ohio. “This multicenter study, which also included cases from Washington University in Saint Louis and Yale-New Haven Hospital, is the largest series of laser ablation for patients with newly diagnosed glioblastoma (GBM) lesions ever conducted and shows that NeuroBlate has an impact on both overall and progression-free survival on patients after surgery. While additional prospective studies are warranted, these preliminary findings are encouraging.”

In the first study, a multicenter review, investigators collected data from 22 patients with newly diagnosed GBM tumors who underwent a procedure with the NeuroBlate System and who had not received prior radiation or chemotherapy. Extent of ablation was defined by software as blue (43 degrees centigrade for 10 minutes) or yellow (43 degrees centigrade for two minutes) thermal-damage threshold (TDT)-lines. Volumetric analysis was performed to determine the extent-of-coverage (EOC) by TDT lines. EOC for yellow and blue TDT-lines was 94% and 91% respectively. Median OS and PFS were 14.7 (range 2.7-44.2) and 5.4 months (range 3.4-9.2) respectively. Regression analysis for OS was significant for EOC by yellow and blue TDT-lines ($p=0.04$ for each), age ($p=0.02$) and pre-operative Karnofsky Performance Status or KPS (a standardized method of measuring the ability of brain tumor patients to perform ordinary tasks; $p=0.04$). Additional analysis demonstrated that EOC by blue TDT-line was still significant for OS when compared with age ($p=0.007$) and had a very good trend ($p=0.08$) versus KPS. Of note, EOC by yellow TDT-line was the only significant factor for PFS (0.047).

Also, as part of the CNS scientific program, investigators from Vanderbilt University presented a case study highlighting their first successful ablation of the hippocampus and amygdala using the NeuroBlate SideFire™ directional laser.

Commenting on the case, Joseph Neimat, M.D., study author and associate professor of neurological surgery noted, “While brain structures with regular shapes can be readily targeted with laser therapy, complex structures have historically posed a challenge with this modality. A directional laser enabled contouring in the hippocampus and amygdala, regions that would otherwise be difficult to ablate. These findings, while preliminary, help lay the foundation for maximally precise, minimally-invasive lesioning of targets in the brain including tumors, seizure foci and low-flow vascular lesions.”

"We are encouraged by the growing body of scientific evidence supporting the use of NeuroBlate as a minimally invasive tool to ablate brain lesions," said John Schellhorn, President and CEO of Monteris Medical. "We are grateful to our clinical collaborators for advancing these studies and presenting their findings at this important scientific forum."

About the NeuroBlate System®

The NeuroBlate System is FDA-cleared to ablate, necrotize or coagulate soft tissue encountered in the discipline of neurosurgery through the application of laser thermotherapy. NeuroBlate is a tool (as opposed to a "treatment") and is not intended to treat any specific disease or lesion type such as GBMs. Physicians should use their clinical judgment and experience when deciding whether to use NeuroBlate.

The NeuroBlate System is considered to be minimally invasive surgery. With the NeuroBlate System, a surgeon makes a small hole in the skull, approximately as wide as a pencil. A small probe is then used to deliver laser light energy to heat and destroy the tumor. The NeuroBlate System combines magnetic resonance imaging (MRI) and software-based visualization to allow surgeons to remotely ablate tumors in many locations in the brain, at the surface or deep inside, through a computer module. An MRI compatible robotic probe driver helps the surgeon precisely guide the laser probe to the tumor and apply heat to it in controlled amounts, until the targeted tissue is destroyed.

With its minimally invasive approach, the NeuroBlate System has shown results analogous to open surgery.[i] Patients undergoing procedures with the NeuroBlate System may experience less pain compared with those undergoing open surgical procedures and reduced hospital length of stay over open surgical procedures.[i,ii,iii]

Since it received clearance from the U.S. Food and Drug Administration (FDA) in April 2013, the NeuroBlate System has been adopted for use in more than 22 leading institutions across the country including Cleveland Clinic, UC San Diego Health System, Barnes Jewish Hospital, Washington University and Yale New Haven Hospital. Monteris Medical supports the installation of new systems with comprehensive hands-on training and ongoing technical support.

Full prescribing information for the NeuroBlate System is available at www.monteris.com.

About Monteris®

Monteris Medical is a privately held company developing devices for minimally-invasive, MR-guided neurosurgery. Monteris markets the NeuroBlate® System for controlled, volumetric ablation of brain lesions. Monteris also offers the various Stereotactic anchoring devices for

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[i] Hawasli AH, Bagade S, Shimony JS, et al. Magnetic resonance imaging-guided focused laser interstitial thermal therapy for intracranial lesions: single-institution series. Neurosurgery. 2013 Dec; 73(6):1007-17.

[ii] Sloan AE, Ahluwalia MS, Valerio-Pascua J, et al. Results of the NeuroBlate System first-in-humans Phase I clinical trial for recurrent glioblastoma: clinical article. J Neurosurg. 2013 Jun; 118(6):1202-19.

[iii] Mohammadi, AM and Schroeder, JL. Laser interstitial thermal therapy in treatment of brain tumors – the NeuroBlate System. Expert Review of Medical Devices 2014 11:2, 109-119.

image-guided trajectory alignment, and the AtamA™ Stabilization System for MR based procedures requiring versatile head fixation.

For more information on Monteris Medical please visit www.monteris.com.

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