

OCTOBER 1, 2014

HEALTH CANADA ISSUES MEDICAL DEVICE LICENSE FOR MONTERIS MEDICAL'S NEUROBLATE SYSTEM

First Minimally Invasive Robotic Laser Thermotherapy Tool for Use in Neurological Surgery

WINNIPEG and PLYMOUTH, Minn. October 1, 2014 -- Monteris Medical announced today that its NeuroBlate® System, a minimally invasive robotic laser thermotherapy tool, has received Health Canada License as a Class 4 Medical Device. The NeuroBlate System employs a pulsed surgical laser to deliver targeted energy to abnormal brain tissue caused by tumors and other neurological soft tissue lesions.

With this recent approval, NeuroBlate is the first and only minimally invasive robotic laser thermotherapy tool available in Canada.

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. With the NeuroBlate System, a surgeon makes a small hole in the skull, approximately as wide as a pencil. The surgeon then precisely guides the small laser probe via an MRI compatible robotic driver to apply controlled amounts of heat to the targeted lesion, until the tissue is destroyed.

"We are excited to launch the first NeuroBlate System in Canada. NeuroBlate represents an exciting new weapon in the field of brain tumors and other neurological soft tissue lesions," said Brian D. Toyota, MD CM MSc FRCSC, Head, Division of Neurosurgery, The University of British Columbia. "We are optimistic that this new technology will give patients improved experiences and outcomes and we look forward to reporting on the first few NeuroBlate cases to be performed in Canada in the coming weeks."

With its minimally invasive and image-guided approach, the NeuroBlate System has shown results analogous to open surgery.¹ 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.^{1,2,3}

"It is particularly gratifying to reach this critical regulatory milestone in Canada, where the NeuroBlate System was initially conceived, and where our staff continues to advance its development," said John Schellhorn, President and CEO of Monteris Medical. "We are proud to offer patients and surgeons a new minimally-invasive tool for brain tumors and other neurological soft tissue lesions, and look forward to supporting medical centers across Canada as they incorporate NeuroBlate into their neurosurgical practices."

¹ 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.

² 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.

³ 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.

Cleared by the U.S. Food and Drug Administration (FDA) in April 2013, the NeuroBlate System has been used in more than 275 surgical procedures in more than 20 leading American institutions across the country, including Cleveland Clinic, UC San Diego Health System, Barnes Jewish Hospital, Washington University and Yale New Haven Hospital.

Already licensed in Canada are Monteris' AXiiiS™ stereotactic anchoring device for image-guided trajectory alignment and the AtamA™ Stabilization System for MR-based procedures requiring versatile head fixation.

Monteris Medical supports the installation of new systems with comprehensive hands-on training, ongoing technical support and awareness/outreach resources. In collaboration with its physician network, the Company is also continuing to contribute to the body of knowledge about the NeuroBlate System in scientific settings with ongoing peer-reviewed studies and reports.

About the NeuroBlate System®

The NeuroBlate System is Health Canada-licensed to necrotize or coagulate soft tissue encountered in the discipline of neurosurgery through the application of laser thermotherapy. Full prescribing information for the NeuroBlate System is available at www.monteris.com.

About Monteris Medical

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 image-guided trajectory alignment, and the AtamA™ Stabilization System for MR based procedures requiring versatile head fixation. Now headquartered in Minneapolis, Minnesota, Monteris was founded in Winnipeg, Manitoba, and maintains a significant portion of its staff and operations there.

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

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