Monteris® Medical Announces FDA Clearance of Laser Probe with Fiber Optic Controlled Cooling for Use with the NeuroBlate® System

New NeuroBlate® Optic™ Laser Probe Replaces Metal Thermocouple with Non-Metallic Fiber Optic Temperature Sensor to Preserve Controlled Cooling and Ablation while Improving Safety Profile

PLYMOUTH, Minn. – Oct. 23, 2018 – Monteris Medical, the leader in minimally invasive image-guided thermal therapy, today announced it has received clearance from the U.S. Food and Drug Administration (FDA) for its NeuroBlate® Optic™ Laser Probe, a laser probe with fiber optic controlled cooling. The NeuroBlate Optic Laser Probe is for use with the NeuroBlate System, a minimally invasive MRI-guided robotic laser thermotherapy for use with brain tumors and epileptic foci.

Martin J. Emerson, president and chief executive officer of Monteris Medical, said, "This is an important milestone for Monteris Medical, as well as the neurosurgeons and patients we serve. The Optic Laser Probe's fiber optic temperature sensor retains the NeuroBlate System's unique ability to deliver ablation and cooling control while also raising the probe's safety profile."

The NeuroBlate Optic Laser Probe platform was designed with patient safety in mind. The new design replaces the metal thermocouple inside the laser probe with a non-metallic fiber optic temperature sensor, thus eliminating any risk of unintended probe heating. Because all patient contacting components of the NeuroBlate Optic Laser Probe are non-metallic, MR scan restrictions issued as part of the field advisory notice in the fall of 2017 are eliminated. Additionally, due to its non-metallic fiber optic temperature sensor, the NeuroBlate Optic Laser Probe allows for more freedom to customize the trajectory during surgical planning and positioning. This feature is especially noteworthy for procedures with challenging target locations. Today's NeuroBlate System continues to feature a 1064 nm wavelength, which delivers controlled heating of targeted ablation zones, allowing for deeper penetration of energy and a slower rate of tissue heating. This controlled heating approach means that over-heating targeted tissue may be prevented.

In addition to the new NeuroBlate Optic Laser Probe for the brain, the NeuroBlate System features exclusive TruTemp™ Technology, which is built to deliver accurate thermography with enhanced visualization. TruTemp Technology uniquely mitigates the factors that may negatively influence MRI thermometry, providing confidence in the accuracy of the ablation zone and added safety assurance. NeuroBlate® Fusion™ Software, the exclusive software intelligence behind the NeuroBlate System, delivers advanced image co-registration tools for assured surgical accuracy, enhanced visualization of the ablation target, and maintains robotic control of the laser probe throughout the ablation.

Since receiving FDA 510(k) clearance in 2013, the NeuroBlate System has been used in more than 2,000 patient procedures across 60 installed systems in the U.S. and Canada, and continues to deliver precision and confidence, which are vitally important during an ablation procedure. The new NeuroBlate Optic Laser Probe is the culmination of many advancements within the NeuroBlate System, resulting in a significant leap forward in minimally invasive brain surgery.

The NeuroBlate System is a minimally invasive robotically controlled laser thermotherapy that uses MRI-guided laser light to ablate unwanted tissue in the brain where the lesion, or abnormal tissue, originates. Unlike traditional brain surgery, a procedure with the NeuroBlate System does not require a large opening in the skull. Instead, doctors create a small hole in the skull, about the diameter of a pencil. While the patient is in the MRI machine, the doctor guides a small laser device (probe) through the hole into the lesion.

The probe delivers laser light energy that heats and destroys the affected tissue. Because the NeuroBlate System is MRI-guided, the neurosurgeon is able to visualize the specific area of the brain to be ablated. The precise nature of the procedure helps to lessen the likelihood of harm to nearby healthy brain tissue.

For more information about Monteris and full prescribing information for the NeuroBlate System, please visit monteris.com.

# # #

About Monteris® and the NeuroBlate® System

Monteris Medical is a privately held company that develops and markets innovative MRI-guided, laser-based systems for the ablation of brain lesions. Current investors include Versant Ventures, SightLine Partners, Birchview Capital, and BDC Capital. The Monteris NeuroBlate System is the only minimally invasive cranial access system that enables a robotic interface for the precise and safe delivery of laser energy. The NeuroBlate System is a tool (as opposed to a "treatment") and is not intended to treat any specific disease. Physicians should use their clinical judgment and experience when deciding whether to use NeuroBlate.

Media Contacts:

Bellmont Partners
Hyedi Nelson
(612) 255-1119
hyedi@bellmontpartners.com

Monteris Medical, Inc.
James Erickson
Chief Financial Officer
(763) 762-2705
jerickson@monteris.com