Integra LifeSciences Receives FDA Clearance for Specific Neurosurgery Indication for CUSA® Clarity

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First and Only Ultrasonic Tissue Ablation System Cleared to Treat Malignant and Benign Tumors, but Not Limited to Meningiomas and Gliomas

PRINCETON, N.J., July 22, 2020 (GLOBE NEWSWIRE) -- Integra LifeSciences Holdings Corporation (Nasdaq:IART), a leading global medical technology company, announced today that it has received FDA clearance for a specific indication for neurosurgery for its CUSA® Clarity Ultrasonic Surgical Aspirator System. The announcement occurs on Glioblastoma Awareness Day, a day dedicated to elevating public understanding of this aggressive and difficult to treat form of cancer.

While the CUSA® system has been used for over 40 years* in neurosurgical applications, this specific neurosurgery indication shows CUSA Clarity can be used safely and effectively in neurosurgery for resection of tumors ranging from soft to firm consistencies, which includes removal of primary and secondary malignant, and benign brain and spinal tumors, including but not limited to, meningiomas and gliomas. FDA clearance is based on a wealth of peer-reviewed clinical publications and 40 years of surgical cases involving resection of brain and spinal tumors.

“Integra has a long history of developing technologies that meet surgeon’s needs for enhanced surgical performance, especially for longer and tougher cases, such as brain tumor resections,” said Mike McBreen, executive vice president and president, Codman Specialty Surgical, Integra LifeSciences. “This specific indication represents our continued commitment to offering neurosurgeons safe and effective products that help them achieve the best outcomes for their patients.”

More than 700,000 patients in the United States are living with some form of brain tumor. The most prevalent types of brain tumor in adults are meningiomas and gliomas (such as glioblastoma, ependymoma, astrocytoma, and oligodendroglioma), which make up 81 percent of malignant brain tumors in adults.[1]

Tumor resection surgery is a common approach to treating cancer patients and surgical resection of a tumor can be performed for many types of cancer. The goal of surgery is to remove the entire tumor, or as much of the tumor as possible.[2] CUSA Clarity Ultrasonic Surgical Aspirator System is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows for selective dissection of target tissue like tumors while preserving vessels, ducts and other delicate structures.

About CUSA Clarity

CUSA Clarity is the latest innovation from the CUSA platform, the pioneer and global leader in ultrasonic tissue ablation. Since its launch in 2017, CUSA Clarity has enjoyed widespread adoption globally, particularly within top neurosurgery and neuropediatric hospital programs in the U.S.,[3] It provides speed, precision, performance and comfort for neurosurgeons. When neurosurgeons face their most difficult cases, CUSA Clarity, a global leader in tissue ablation, is a quick and safe way to debulk the toughest tissue at a 160 percent faster rate versus a leading competitor.[4]

Learn more about how CUSA Clarity can make a difference. Click here to visit the CUSA Clarity webpage for further information and indications.

About Integra

Integra LifeSciences is a global leader in regenerative technologies, neurosurgical and extremity orthopedic solutions dedicated to limiting uncertainty for clinicians, so they can focus on providing the best patient care. Integra offers a comprehensive portfolio of high quality, leadership brands that include AmnioExcel®, Bactiseal®, Cadence®, Certas®, Codman®, CUSA®, DuraGen®, DuraSeal®, ICP Express®, Integra®, MediHoney®, MicroFrance®, PriMatrix®, Salto Talaris®, SurgiMend®, TCC-EZ®, Titan™ and VersaTru®. For the latest news and information about Integra and its brands, please visit www.integralife.com.

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ from predicted results. Forward-looking factors that may be discussed include, but are not limited to, future financial performance, new product development, governmental approvals, market potential as well as potential therapeutic applications. These risks and uncertainties include market conditions and other factors beyond the Company's control and the economic, competitive, governmental, technological and other factors identified under the heading "Risk Factors" included in item 1A of Integra's Annual Report on Form 10-K for the year ended December 31, 2019 and information contained in subsequent filings with the Securities and Exchange Commission, including, without limitation, Integra’s Report on Form 10-Q filed on May 7, 2020, could affect actual results. These forward-looking statements are made only as the date thereof, and the Company undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

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[1] American Brain Tumor Association.

[2] Temple Health Tumor Resection Surgery.
* Publications submitted to FDA for CUSA neuro use dated back to 1978

[3] Based on U.S. News and World Report rankings of Best Neuro and Neuro Pediatric Hospitals.

[4] Integra LIfeSciences. Data on File. On average, with Power Handpiece and Tough Tissue Tip, compared with leading competitor's similar handpiece and tip. † On average, with Power Handpiece and Bone Tip, compared with leading competitor's similar handpiece and tip.