FDA Approves Cordis Trufill® n-BCA Liquid Embolic Treatment System For Cerebral 'AVMs'

MIAMI, Sept. 26 -- Cordis Neurovascular today reported U.S. Food and Drug Administration (FDA) approval of the Company's new TRUFILL® n-BCA* Liquid Embolic System for presurgical embolization of cerebral arteriovenous malformations (AVMs: a tangle of abnormally connecting arteries and veins). Cordis Neurovascular, Inc. (CNV)** is a unit of Cordis Corporation, a Johnson & Johnson company.

Thousands of patients suffer from hemorrhagic stroke each year. Although AVMs occur in less than 1% of the population, there is risk of severe neurologic deficit or death if they are left untreated. Approximately 20 - 30% of brain AVM patients are initially seen by physicians for seizures, and up to 15% for chronic headaches. Risk of hemorrhage from cerebral AVMs is 2 - 4% per year, increasing to 6 - 15% per year in the first year after a single hemorrhage. The risk of neurological deficit following hemorrhage is 20 - 30%.

Cordis' TRUFILL n-BCA Liquid Embolic System is an artificial embolization device, comprised of TRUFILL n-Butyl Cyanoacrylate (n-BCA), TRUFILL Ethiodized Oil, and TRUFILL Tantalum Powder. These components are combined to form a mixture that is injected through a microcatheter to embolize AVMs prior to surgical resection. Although the mixture is liquid during delivery, it hardens to form a solid material on contact with blood at the site of the AVM in the brain.

While n-BCA has been available to neurointerventionalists - physicians who treat neurovascular disorders and disease - under FDA discretionary policy for quite some time, Cordis completed a clinical trial at the urging of numerous physicians nationwide to bring the technology to approval and full medical use.

"TRUFILL n-BCA enhances our ability to use microcatheters and flow-guided catheters to embolize AVMs in the brain," said Tom Tomsick, M.D., Principal Clinical Investigator, of the University of Cincinnati School of Medicine. "In addition," he said, "this technology provides physicians with the ability to deliver radiopaque embolic material to the nidus (interconnecting network of arteries and veins comprising the main body of the AVM, within the brain)."

"Design of the TRUFILL n-BCA system provides physicians with the flexibility to optimize it to a patient's medical needs, or circumstances," said Phillip Purdy, M.D., of The University of Texas - Southwestern Medical School, Dallas. "Patient care will be significantly improved by its availability.

"I am very pleased with the ease in which TRUFILL n-BCA liquid can be delivered," Dr. Purdy continued. "For patients, the outcome may be a life-saving procedure."

In addition to Drs. Tomsick and Purdy, a number of other globally recognized interventional practitioners participated in clinically evaluating the n-BCA technology throughout its development. In Sup Choi, M.D., of Lahey Clinic, Burlington, MA, said, "TRUFILL n-BCA is a great tool for management of brain AVMs."

"Our introduction of the TRUFILL n-BCA technology is one of a number of anticipated new innovations in development by Cordis Neurovascular that are designed to provide better therapeutic outcomes for physicians and their patients, " said Ed LeMoure, International Vice President, Johnson & Johnson, and Worldwide General Manager of Cordis Neurovascular, Inc.

"Our TRUFILL n-BCA Liquid Embolic System offers physicians a presurgical alternative that may optimize AVM interventions," said Jan Keltjens, U.S. General Manager, Cordis Neurovascular. "This product will be readily available shortly and is designed to be compatible with Cordis Neurovascular delivery catheters, including our REGATTA® Flow Guided Infusion Catheter, as well as our PROWLER®, and TRANSIT® microcatheters," Mr. Keltjens said.

Based in Miami Lakes, FL, CNV is a unit of Cordis Corporation, a broad-based global supplier of leading edge therapies and technologies for circulatory disease management, including interventional medicine, diagnosis and treatment, and electrophysiology. Established in 1959, Cordis Corporation, along with its subsidiaries, merged with Johnson & Johnson in 1996 and now has approximately 3,500 employees worldwide.

n-BCA: n-Butyl Cyanoacrylate

** NOTE: Cordis Neurovascular, Inc. (CNV) develops, manufactures and

markets medical devices for the brain - neurovascular applications. In order to more clearly define and link its identity with its technology and products, the Company recently changed its name to Cordis Neurovascular, Inc., a Johnson &

Johnson company, from Cordis Endovascular Systems, Inc. (CES).

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