Boston Scientific

Boston Scientific Launches Clinical Trial to Study Endovascular Treatment of Brain Aneurysms

NATICK, Mass., Oct. 16 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced the initiation of a new clinical trial designed to identify and investigate clinically relevant endpoints for evaluating the efficacy and durability of endovascular treatment of brain aneurysms.

The MAPS trial (Matrix And Platinum Science) is a prospective, multi-center study that is designed to randomize approximately 600 patients at 50 global centers for treatment of brain aneurysms. Patients will be randomized to receive either Matrix2™ Detachable Coils or GDC® Detachable Coils. To promote scientific integrity, the trial design includes independent angiographic core lab assessment, adjudication of adverse events by medical reviewers blinded to the treatment modality utilized, and randomization of cases based upon rupture status to minimize selection biases. The trial's primary endpoint is target aneurysm recurrence (TAR), which is a composite endpoint comprised of target aneurysm reintervention, target aneurysm rupture or re-rupture or death related to the target aneurysm or procedure.

Boston Scientific manufactures GDC coils, the first bare-platinum detachable coil cleared for aneurysm treatment, as well as Matrix2 coils, which are covered with a polyglycolic-polylactic acid (PGLA) bio-polymer shown to improve treatment durability in preclinical studies.

"The launch of the MAPS trial demonstrates our commitment to understanding the efficacy and durability of endovascular therapies for the treatment of brain aneurysms," said Milt McColl, President, Boston Scientific Neurovascular. "By including both technologies in the study, we will establish a baseline of data to support future research involving endovascular treatment of aneurysms with bare platinum and bio-polymer covered coils."

The trial will feature a multi-disciplinary team of Principal Investigators, including S. Claiborne Johnston, M.D., Ph.D., UCSF Medical Center in San Francisco, California; Cameron McDougall, M.D., Barrow Neurological Institute in Phoenix, Arizona; and Professor Jacques Moret, Fondation Ophthalmologique Adolphe De Rothschild in Paris, France.

"Today, physicians rely on visual interpretation of angiographic images and other subjective methods to judge the success of coiling procedures," said Stanley L. Barnwell, M.D., Ph.D., Associate Professor of Neurological Surgery and the Dotter Interventional Institute Oregon Health and Sciences University, a member of the MAPS trial Steering Committee. "The MAPS trial is designed to identify clinically relevant endpoints that can be used to validate, or invalidate these clinical proxies and determine new, more empirical ways to measure the success of these innovative procedures."

"MAPS is helping set a new standard for the field," added Dr. Johnston. "It's great that Boston Scientific is willing to invest in high quality data and in improving the tools for use in the next-generation aneurysm treatment trials."

The Company expects to begin enrolling patients by the end of 2006.

About brain aneurysms

A brain aneurysm is a weakened bulge in the wall of an artery in the brain. It is estimated that up to one in 15 people in the U.S. will develop a brain aneurysm during their lifetime. When a brain aneurysm ruptures, it can bleed into the subarachnoid space around the brain resulting in a subarachnoid hemorrhage (SAH). The prevalence of SAH in the U.S. exceeds 30,000 people annually. Fifty percent of these patients will die as a result of the rupture. Of those who survive, about half will suffer permanent physical or mental disability. Currently, brain aneurysm patients have two treatment options: conventional surgical clipping, and endovascular coiling, a newer, less-invasive technique.

Endovascular coiling does not require open surgery. Instead, physicians use a real-time X-ray technology, called fluoroscopy, to visualize the patient's vascular system and access the aneurysm from within the artery itself. To perform this procedure, a microcatheter (small plastic tube) is inserted into an artery in the patient's leg and navigated through the vascular system, up into the head, and into the aneurysm. Then, tiny coils are fed through the microcatheter and deployed within the aneurysm to block the flow of blood into the aneurysm and prevent rupture. The coils are made of platinum so that they are visible under fluoroscopy and pliable enough to conform to the aneurysm shape. More than 200,000 patients worldwide have been treated with detachable platinum coils.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: http://www.bostonscientific.com/.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with clinical trials, intellectual property, regulatory approvals, competitive offerings, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

CONTACT: Milan Kofol
508-650-8569
Investor Relations
Boston Scientific Corporation

Paul Donovan
508-650-8541
Media Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Milan Kofol, Investor Relations, +1-508-650-8569, or Paul Donovan, Media Relations, +1-508-650-8541, both of Boston Scientific Corporation

Web site: http://www.bostonscientific.com/

---

https://news.bostonscientific.com/launch-trial-endovascular-brain-aneurysms