Boston Scientific

Boston Scientific Welcomes Results of Brain Aneurysm Clinical Trial

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Risk of death at five years is lower for aneurysm patients treated with coil embolization compared to surgical clipping

NATICK, Mass., May 26 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed publication of results from the ISAT clinical trial in The Lancet Neurology showing patients with a ruptured intracranial aneurysm treated with endovascular coil embolization are 23 percent less likely to die within five years compared to patients who undergo surgical clipping. The findings are reported by Andrew Molyneux, M.D., and Richard Kerr, M.D., from the Neurovascular and Neuroradiology Research Unit of the John Radcliffe Hospital, Oxford, and University of Oxford, U.K.

ISAT is the only multicenter, prospective, randomized controlled clinical trial comparing the safety and efficacy of coil embolization and surgical clipping in the treatment of ruptured brain aneurysms. The latest ISAT data assessed the risk of death and re-bleeding after treatment in more than 2,000 patients with a mean follow-up of nine years.

At five years post-treatment, 14 percent of surgically clipped patients had died compared to 11 percent of patients treated with endovascular coiling, representing a 23 percent relative reduction in risk of death for coiled patients. The percentage of patients characterized as independent in their daily activities at five years post-treatment was similar for both groups (82 percent for coiling versus 81 percent for clipping).

"The recently published ISAT data are reassuring to both patients and physicians," said Dr. Molyneux, Principal Investigator for ISAT. "The risk of late bleeding from a coiled aneurysm is very low, which has been a clinically unanswered question in the medical community. Although there was a slightly greater chance of re-bleeding from a coiled aneurysm in the first five years, fewer coiled patients died at five years, and there have been no observed hemorrhages from a coiled aneurysm in these patients after five years."

"The extraordinary work by Drs. Molyneux and Kerr and the ISAT investigators represents a milestone in the evolution of treatment for cerebral aneurysms," said Mark Paul, President, Boston Scientific Neurovascular. "The data from ISAT over the last six years have informed the worldwide neurovascular community and helped physicians better determine the best treatment options for patients suffering from a ruptured aneurysm."

The primary objective of ISAT was to determine whether endovascular treatment reduced the rates of patient death or dependency at one year compared with surgical treatment. The trial, supported by the U.K.'s Medical Research Council (MRC), began as a pilot study in 1994 and enrolled 2,143 patients at 43 neurosurgical centers who were randomly assigned to coiling or clipping. Patients were primarily treated with the early generation of Boston Scientific's GDC® Coils, some as far back as 14 years when technology, angiographic imaging equipment and physician experience differed significantly from today. One-year results reported in 2002 demonstrated a 24 percent relative risk reduction in death or dependency in patients treated with endovascular coiling compared to surgical clipping, which is consistent with five-year results.

"ISAT has required the dedication of doctors, nurses, trial staff, patients and their relatives over many years, and we are extremely grateful to them all," said Dr. Molyneux. "The positive trial results should reassure patients and physicians that treatment with endovascular coiling is safe in the short term while also providing a long-term benefit of lower death risk compared to surgical intervention. The latest data continue to support the general shift toward coiling for the treatment of brain aneurysms."

Endovascular coiling is a minimally invasive procedure in which tiny, platinum coils are inserted via catheter through the blood

vessels into the aneurysm to prevent further bleeding into the brain. Surgical clipping is an open intervention involving a significantly longer recovery time, in which a small clip is placed across the aneurysm.

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: www.bostonscientific.com.

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This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding clinical trials, regulatory approvals, competitive offerings and product performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

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CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

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