

## **Boston Scientific Receives FDA Approval for Clinical Trial of its Liberté™ Paclitaxel-Eluting Coronary Stent System**

(July 22, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received an Investigational Device Exemption from the U.S. Food and Drug Administration (FDA) to begin its ATLAS clinical trial. ATLAS is the first clinical trial using Boston Scientific's new Liberté coronary stent as a platform for its paclitaxel-eluting coronary stent system. TAXUS™ Liberté will be the next generation to Boston Scientific's current paclitaxel-eluting stent system, TAXUS™ Express<sup>2</sup>™. The Liberté stent, which has been designed to further enhance deliverability and conformability, particularly in challenging lesions, is currently available in international markets in a bare metal version.

The ATLAS trial is a pivotal study to collect data to support regulatory filings for product commercialization. It is designed to assess the safety and efficacy of a slow-release dose formulation paclitaxel-eluting TAXUS Liberté stent system for the treatment of coronary artery disease. The trial is scheduled to enroll 822 patients at 60 sites in the United States, Canada, Australia, New Zealand, Singapore, Hong Kong and Taiwan.

"I have found the Liberté bare metal stent to be an excellent stent with superb conformability and deliverability," said Keith Dawkins, M.D., Consultant Cardiologist, Wessex Cardiothoracic Centre, Southampton University Hospital, Southampton, England. "I am looking forward to Boston Scientific's next-generation paclitaxel-eluting stent, which will use this platform."

"We are excited to be moving forward with the pivotal study for our next-generation paclitaxel-eluting coronary stent system," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "The Liberté system will feature the proven efficacy of paclitaxel, together with an outstanding stent and an enhanced delivery system. It will represent yet another advance in the treatment of coronary artery disease."

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](http://www.bostonscientific.com).

This press release contains forward-looking statements. The Company 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 commercialization of new technologies, competitive offerings, intellectual property and other factors described in the Company's filings with the Securities and Exchange Commission.

---

<https://stage.mediaroom.com/bostonscientific/news-releases?item=58631>