Cordis Receives FDA Approval for EXOSEAL™ Vascular Closure Device

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Cordis Corporation, a worldwide leader in the development and manufacture of interventional vascular technology, today announced the approval of the EXOSEAL™ Vascular Closure Device in the US. EXOSEAL™ incorporates a number of new advances in technology and simplicity of design to provide precise and secure extravascular arterial closure.

EXOSEAL(TM) Vascular Closure Device (Photo: Business Wire)

"We are very pleased to announce the approval of our first Vascular Closure Device in the United States" said Campbell Rogers, M.D., Chief Scientific Officer and Global Head, Research and Development, Cordis Corporation. "EXOSEAL™ has demonstrated excellent clinical efficacy and safety but also incorporates key design advancements intended to promote safety, ease of use and patient comfort. We are looking forward to building upon the outstanding experience that clinicians and patients have had outside the US since June 2010 when EXOSEAL™ received CE mark in Europe."

The ECLIPSE Trial

The safety and effectiveness of EXOSEAL™ was assessed in the U.S. in the ECLIPSE trial where was compared with manual compression (MC) with a 2:1 randomization in patients undergoing diagnostic and interventional coronary/peripheral procedures. The trial tested the time to hemostasis, the time to ambulation and the 30-day combined rate of access site-related complications.

"From our experience in the ECLIPSE trial, this new closure device proved to be safe and effective. The results showed that the use of EXOSEAL™ significantly reduced time to ambulation compare to MC. There were no major adverse events, no vascular repair, no access site-related bleeding requiring transfusion and no access site-related infection requiring treatment. Based on these results, we believe that use of EXOSEAL™ will benefit patients by shortening the time to ambulation, with a low rate of complications. In addition, the device has easy-to-use functionality," said S. Chiu Wong, M.D., Primary Investigator, New York-Presbyterian Hospital/Weill Cornell Medical Center, New York.

These thoughts were also echoed by another Primary Investigator in the ECLIPSE trial, William Bachinsky, M.D., Pinnacle Health at Harrisburg, Harrisburg, Pennsylvania who said, "The EXOSEAL™ device offers unique features compared to current available closure devices. They include the use of a fully bioabsorbable PGA plug which means that nothing is left inside the artery to impede arterial blood flow. The two visual indicators and lockout feature provide additional measures to help ensure precise extravascular placement. Because of the design there is minimal tugging and pulling required which could help to improve patient comfort during closure."

U.S. Commercialization:

The EXOSEAL™ Vascular Closure Device is due to be available to the commercial market in June in the United States. It has been available in Europe, Asia and Latin American markets since June, 2010. Cordis will roll out a comprehensive program of customer training to provide users with experience and confidence in the handling and utilization of the device.

EXOSEAL™ in detail

The EXOSEAL™ Vascular Closure Device makes use of key technological developments to support the clinical safety of the closure procedure. In the ECLIPSE Trial, the extravascular plug placement was associated with no embolization, infection or other major adverse events, comparable to manual compression [despite the significantly shorter time to ambulation for EXOSEAL™]. The bioabsorbable PGA-plug, which is designed to close the femoral artery puncture site with minimal or no inflammation, is fully reabsorbed in 60-90 days. PGA (Polyglycolic Acid) is a trusted non-collagen plug material that is metabolized to carbon dioxide and water. A system of deployment through the existing procedural sheath helps make EXOSEAL™ quick and easy to use, and increases physician convenience since there is no need for sheath exchange during the procedure. The device uses visual indicators to help the clinician deploy the device correctly. This "visual feedback" also promotes patient comfort during deployment by minimizing tugging and pulling and the 'lock-out' system of EXOSEAL™ helps clinicians to achieve proper extra-vascular plug placement.

Drs. Chiu Wong and Bachinsky provide consulting services to the company and are compensated for their work.

About Cordis Corporation

For more than 50 years, Cordis Corporation, a Johnson & Johnson company, has been a worldwide leader in the development and manufacture of interventional vascular technology. Through the company's innovation, research and development, Cordis partners with interventional cardiologists worldwide to treat millions of patients who suffer from vascular disease.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Cordis Corporation and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Cordis Corporation nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

Photos/Multimedia Gallery Available: http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6732303&lang=en

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Source: Cordis Corporation