St. Jude Announces First Implant Evaluating New Size of Portico Heart Valve in European Trial

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Feb 4, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the first patient implant of its 25 mm Portico Transcatheter Aortic Heart Valve using the Transfemoral Delivery System in its ongoing European trial. The Portico valve system offers a minimally invasive treatment option for patients with severe aortic stenosis – a narrowing of the aortic valve that obstructs blood flow from the heart.

25 mm Portico(TM) Transcatheter Aortic Heart Valve (Photo: St. Jude Medical) The Portico Trans femoral European Trial (Portico TF EU Trial) was established to evaluate the 23 mm Portico valve, which recently received European approval, and has been expanded to include the 25 mm Portico valve.

A non-randomized, multi-center study, the Portico TF EU Trial will evaluate the safety and performance of the Portico 25 mm transcatheter heart valve in patients with severe aortic stenosis. The trial will enroll up to 50 patients across Europe. Data from the study will be used to support CE Mark approval.

Expanding the Portico TF EU trial to include the 25 mm Portico valve size allows physicians to increase their research of the technology in patients whose anatomy requires a larger valve size.

Made of bovine pericardial tissue, the Portico valve is attached to a self-expanding stent frame. It is the only approved transcatheter valve that can be completely resheathed (the process of bringing the valve back into the delivery catheter), repositioned at the implant site, or retrieved before being released from the delivery system.

Transcatheter heart valves like Portico are used to treat patients with severe aortic stenosis. These patients often are too sick and have co-morbidities that prevent them from having conventional open-heart valve replacement surgery. The Portico valve helps to restore normal blood flow and provides an innovative and life-saving treatment option.

During a transcatheter procedure using the transfemoral delivery system, a physician implants the Portico valve through a catheter which has been placed through a small incision in the artery of the leg in order to gain access to the heart.

“The start of the Portico TF EU Trial for the 25 mm Portico valve is another major milestone in our transcatheter valve program and an indication of our commitment to provide new options to patients suffering from aortic valvular heart disease,” said Frank J. Callaghan, president of the Cardiovascular and Ablation Technologies

Division at St. Jude Medical.

The Portico Transcatheter Aortic Heart Valve and Transfemoral Delivery System are not yet approved for use in the United States. A U.S. clinical trial evaluating the Portico valve is expected to start later this year. The trial will be conducted under a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE).

It is estimated that as many as 400,000 people worldwide are affected by severe aortic stenosis, a potentially life-threatening condition where the aortic heart valve becomes calcified and does not open widely enough.

For additional information about the Portico valve visit SJMPortico.com [1].

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