ABBOTT'S OMNILINK ELITE® VASCULAR BALLOON-EXPANDABLE STENT SYSTEM RECEIVES FDA APPROVAL FOR TREATMENT OF ILIAC ARTERY DISEASE

-- Approval Based on Positive Clinical Evidence From the MOBILITY Study, Involving Real-World Patients with Complex Disease
-- Leverages Abbott’s Market-Leading MULTI-LINK Stent Design and Cobalt Chromium Alloy for the Treatment of Iliac Artery Disease
-- Expands Abbott’s Offerings of Innovative Therapies for Treatment of Peripheral Artery Disease, a Major Focus for the Company

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ABBOTT PARK, Ill., Aug. 7, 2012 /PRNewswire/ -- Abbott today announced that the U.S. Food and Drug Administration (FDA) approved the Omnilink Elite® Vascular Balloon-Expandable Stent System for the treatment of iliac artery disease, a form of peripheral artery disease (PAD) that affects the lower extremities. Iliac artery disease can progress to where patients experience chronic pain and reduced ability to walk, potentially leading to permanent disability. The FDA approval is supported by positive clinical data from the MOBILITY (Omnilink Elite or Absolute Pro® Stent Used in the Iliac Artery) study. The MOBILITY study demonstrated that Omnilink Elite is safe and effective, including when used for patients who are difficult-to-treat due to complex disease resulting from severely calcified lesions.

The Omnilink Elite stent is based on the proven, market-leading MULTI-LINK stent design with a next-generation cobalt chromium alloy. Cobalt chromium is stronger and more radiopaque than stainless steel, making the stent easy to see under X-ray while maintaining thin, flexible struts. These features are designed to enable the physician to navigate the stent in complex anatomy and facilitate accurate placement of the device – important for long-term patient outcomes.

"The MOBILITY study demonstrated that treatment with Omnilink Elite resulted in an increase in quality of life in a difficult-to-treat patient population that is reflective of real clinical practice. At nine months, patients experienced significant improvements in walking distance and speed, and were able to climb more stairs than they could before treatment," said Tony S. Das, M.D., FACC, director, Peripheral Vascular Interventions, Cardiology Section, Presbyterian Heart Institute in Dallas, Texas, and co-principal investigator of the MOBILITY study. "Improving patient quality of life continues to be a key objective in the treatment of PAD. With MOBILITY, we have new evidence that we can successfully treat patients with severe lesions with Omnilink Elite and achieve meaningful clinical results."

The MOBILITY study, a prospective, non-randomized, two-arm, multi-center study conducted at 48 centers in the United States, evaluated the effectiveness of two Abbott stents – Absolute Pro Vascular Self-Expanding Stent System and Omnilink Elite Vascular Balloon-Expandable Stent System – in patients who had iliac artery disease with intermittent claudication or critical limb ischemia, including complex lesions. The study is reflective of real-world clinical practice because it did not exclude patients with highly calcified lesions or severe peripheral vascular disease. Of the 304 patients enrolled in the study, 151 were treated with Absolute Pro and 153 were treated with Omnilink Elite. The study met its primary endpoint: a nine-month major adverse event rate of 6.1 percent for patients treated with Absolute Pro and 5.4 percent for patients treated with Omnilink Elite. These rates were significantly below the primary endpoint goal of 19.5 percent (p<0.0001), which was developed from published literature on previous iliac artery stenting studies. The major adverse event rate was defined as death due to any cause, heart attack (myocardial infarction), clinically driven target lesion revascularization and limb loss (major amputation only) on the treated side(s). Walking ability significantly improved for patients in both arms of the study.

"Omnilink Elite was shown to be safe and effective in the MOBILITY study, which evaluated patients with complex disease, including disease caused by severe calcification. Low rates of target lesion revascularization and significant improvements in walking ability reinforce the use of Omnilink Elite in real-world patients," said Charles A. Simonton, M.D., FACC, FSCAI, divisional vice president, Medical Affairs, and chief medical officer, Abbott Vascular. "Abbott is dedicated to improving the lives of patients with PAD by providing physicians with the most innovative therapies for treatment of this debilitating disease. The approval of Omnilink Elite and the recent FDA
approval of Absolute Pro add to Abbott's already robust portfolio of advanced endovascular products for the treatment of PAD."

Omnilink Elite is the newest addition to Abbott's U.S. portfolio of endovascular products for the treatment of PAD, including balloon dilatation catheters to treat blockages in the lower extremities and vascular stents to open blocked kidney and carotid arteries.

**About PAD and Iliac Artery Disease**

Peripheral artery disease affects approximately 8 million to 12 million people in the United States and occurs when the blood vessels outside of the heart become narrowed with plaque, fatty deposits that build up within the vessels.\(^1\) While PAD is most commonly seen in the legs, blockages can also occur in the vessels that carry blood to the head, arms, kidneys and stomach.

Aortoiliac occlusive disease, more commonly known as iliac artery disease, occurs when the iliac arteries become narrowed with plaque, resulting in reduced blood flow to the lower limbs. Iliac artery disease is a type of PAD. While PAD refers to all of the arteries outside of the heart, iliac artery disease refers specifically to the arteries that start in the mid-abdomen – where the body's main artery (the aorta) splits into branches that descend through the pelvis into the legs.\(^2\) Iliac artery disease is caused by plaque build-up in one or more of these major arteries: the common iliac, internal iliac (hypogastric) or the external iliac.

**About the Omnilink Elite Vascular Balloon-Expandable Stent System**

In the United States, the Omnilink Elite Vascular Balloon-Expandable Stent System is indicated for the treatment of atherosclerotic iliac artery lesions with reference vessel diameters of ≥ 5.0 mm and ≤ 11.0 mm, and lesion lengths up to 50 mm. Specific information about the Omnilink Elite Vascular Balloon-Expandable Stent System, including important safety information, is available online at:


**About the Absolute Pro Vascular Self-Expanding Stent System**

In the United States, the Absolute Pro Vascular Self-Expanding Stent System is indicated for improving luminal diameter in patients with *de novo* or restenotic atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters between 4.3 mm and 9.1 mm and lesion lengths up to 90 mm. Specific information about the Absolute Pro Vascular Stent System, including important safety information, is available online at:

http://www.abbottvascular.com/static/cms_workspace/pdf/ifu/peripheral_intervention/eIFU_Absolute_Pro.pdf

Omnilink Elite and Absolute Pro are available in the United States, Europe, the Middle East and parts of Asia. Indications vary by geography. Balloon-expandable stents and self-expanding stents differ in how they are delivered to the lesion. Physicians typically choose which type of stent to use based on lesion location, complexity and the long-term prognosis of the patient.

**About Abbott Vascular**

Abbott Vascular is the world's leader in drug eluting stents. Abbott Vascular has an industry-leading pipeline and a comprehensive portfolio of market-leading products for cardiac and vascular care, including products for coronary artery disease, vessel closure, endovascular disease and structural heart disease.

**About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 91,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

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\(^2\) [http://www.vascularweb.org/vascularhealth/Pages/aortoiliac-occlusive-disease.aspx](http://www.vascularweb.org/vascularhealth/Pages/aortoiliac-occlusive-disease.aspx)