Devax Receives IDE Approval to Commence DIVERGE II

Irvine, CA – May 29, 2009 - Devax, Inc. today announced that the U.S. Food and Drug Administration has conditionally approved an Investigational Device Exemption ("IDE") for its AXXESS™ Biolimus A9® Eluting Bifurcation Stent System (AXXESS System), allowing the company to initiate a pivotal clinical trial (DIVERGE II) of the device in the United States.

The DIVERGE II study is a multicenter, blinded, controlled, randomized trial comparing the treatment of bifurcation lesions with the AXXESS stent to standard techniques with conventional stents. The Principal Investigator is Jeffrey Moses, M.D., Professor of Medicine and Director of the Center for Intravascular Therapy at Columbia University Medical Center in New York.

Bifurcation lesions occur in approximately 20% of patients that are treated for ischemic heart disease with coronary angioplasty and stenting. Recent large scale clinical studies, such as SYNTAX and LEADERS, have shown that lesions located at vessel bifurcations increase the frequency of major adverse cardiac events by as much as 40% compared to lesions in straight vessel segments. Currently, there is no stent with an FDA approved indication for use in bifurcation lesions.

Devax has implanted over 430 AXXESS stents in two clinical studies conducted outside the United States. The second of these studies, DIVERGE I, enrolled 302 patients at 16 clinical centers in Europe, Australia, and New Zealand. The 9 month follow up for these patients was presented last October at the Transcatheter Therapeutics conference in Washington, DC. The data, published in the March 23, 2009 issue of the Journal of the American College of Cardiology, show high rates of clinical success and low rates of restenosis compared to other studies of bifurcations.

Discussing the significance of the study, Professor Moses said, “DIVERGE II will be a landmark study because there are many novel aspects to the trial. The AXXESS stent is the first drug eluting stent dedicated solely to bifurcation lesions. We see these types of lesions frequently in daily practice, and they are difficult to treat with conventional stents and techniques. Also, this study is the first randomized study to compare a lesion-specific drug eluting stent to a standard device in a complex vessel anatomy”.

"This is the first IDE approval of a drug eluting stent specifically designed for use in coronary bifurcations", said Jeff Thiel, President and CEO. “We have focused our attention on being the first to market in the United States with a dedicated DES, and this is an important step toward that goal.”

The Devax AXXESS System technology is a proprietary self-expanding Nitinol stent specifically designed for the treatment of coronary and vascular bifurcation lesions. The

conical shape of the stent is designed to conform to the bifurcation anatomy and provide full access to both branches for additional interventional procedures.

Devax, Inc., a private emerging medical device company located in Irvine, California, is engaged in the development of solutions for the treatment of atherosclerotic disease in coronary arteries.

For further information, contact:

Jeff Thiel
President & CEO
949-461-0450