

Infraredx to launch TVC Imaging System in Japan

28 June 2012 | News | By BioSpectrum Bureau

Infraredx to launch TVC Imaging System in Japan



Singapore: Infraredx, a medical device company committed to advancing the diagnosis and management of coronary artery and other vascular diseases, has signed an exclusive five-year agreement with Nipro to distribute the TVC Imaging System for true vessel characterization of coronary artery disease in Japan.

This agreement expands Infraredx's presence into Asia and demonstrates the company's commitment to make the TVC Imaging System available worldwide. The TVC Imaging System is a first-in-class intravascular imaging system that integrates near infrared spectroscopy (NIRS) lipid core plaque (LCP) detection and enhanced intravascular ultrasound (IVUS) imaging technology to assess vessel composition and structure.

Under the terms of the agreement, Infraredx will receive a minimum of \$50 million in revenues over the duration of the agreement. Nipro will be responsible for obtaining marketing authorization for the TVC Imaging System and catheter with Japan's Pharmaceuticals and Medical Device Agency (PMDA). Additionally, Nipro will be responsible for all sales, marketing and promotion of the TVC System, including clinical education and physician training in the operation of the TVC system as well as all field service and technical support of the TVC System. The agreement is contingent upon a Shonin (product approval) by the Japanese regulatory authorities. The companies anticipate approval and subsequent launch of the TVC Imaging System in Japan in 2013.

"Japan is the world's largest intravascular imaging market and as such represents a tremendous commercial opportunity for Infraredx," said Mr Donald Southard, president and chief executive officer of Infraredx. "Our agreement with Nipro is another major milestone in our global commercialization strategy as we continue to expand access to the TVC Imaging System. As a global life sciences leader, Nipro is the perfect partner to bring the TVC Imaging System to the Japanese market. The company has extensive in-depth knowledge of the medical device and cardiovascular imaging space, and is committed to providing innovative products that meet the needs of healthcare professionals and improve the quality of life for patients."

IVUS has become the standard of care in Japan with more than 80 percent of all percutaneous coronary intervention (PCI) procedures guided by intravascular imaging. However, while IVUS can display the structure of a plaque, it is not an optimal method to determine its composition and if it contains a lipid core. Lipid core plaque is a fatty coronary artery plaque suspected to be vulnerable to rupture and cause most heart attacks. It is also known to complicate stenting procedures either during or following the placement of coronary artery stents. The TVC Imaging System is the only device that offers physicians both IVUS and NIRS to improve characterization of the vessel.

"We are delighted to partner with Infraredx on the sales and marketing of the TVC Imaging System in Japan," said Mr Yoshihiko Sano, president of Nipro. "We have received positive feedback from Japanese interventional cardiologists on the clinical value of the TVC Imaging System and its unique intravascular imaging capabilities. The device enables physicians to identify lipid core plaque in patients who are at risk of developing stenting complications during PCI, which can lead to more precisely tailored treatment strategies. We plan to submit the regulatory package to the PMDA in the coming weeks and look forward to introducing the TVC Imaging System to the market next year."