



## **InfraReDx Receives European CE Mark Approval of LipiScan™ IVUS Coronary Imaging System**

### ***Company Achieves Key Milestone in Global Commercialization Strategy***

**BURLINGTON, Mass. – April 20, 2011 – InfraReDx, Inc.**, a medical device company providing intelligent cardiovascular diagnostic imaging technologies, today announced it has received CE Mark approval to begin commercialization of the LipiScan™ IVUS Coronary Imaging System throughout Europe. With CE Mark approval, the LipiScan IVUS system is the only device available in both the U.S. and Europe for the detection of the plaques known to complicate stenting and believed to be the reason for most heart attacks.

“Receipt of the CE Mark for the LipiScan IVUS system is an important regulatory milestone for InfraReDx as we advance our global commercialization strategy to make this novel product available to physicians worldwide,” said Donald Southard, president and chief executive officer of InfraReDx. “With the U.S. launch of the system well underway, we are already receiving tremendous interest from physicians in Europe and are in active discussions with prospective distributors of the product. We are currently finalizing our European marketing plan and expect to launch the LipiScan IVUS in select countries in the coming months.”

The LipiScan IVUS Coronary Imaging system received U.S. Food and Drug Administration (FDA) approval in June 2010. The system includes the world’s first and only cardiac catheter to combine intravascular ultrasound (IVUS) and near-infrared (NIR) spectroscopy to help cardiologists identify and characterize lipid core coronary plaques. In a single catheter pullback, the LipiScan IVUS provides physicians with a traditional IVUS image that clearly displays key structural parameters of the lesion, including its location, length, and degree of stenosis, in addition to confirming proper stent placement. At the same time, the system performs spectroscopic analysis of optical data to produce a Chemogram™ map that indicates the location of lipid core plaques and quantifies their lipid core burden. Integrating and co-registering the Chemogram with IVUS provides critical information to interventional cardiologists during the cardiac catheterization procedure.

“The LipiScan IVUS system is an important new intravascular imaging tool that will be of immediate value to interventional cardiologists for the diagnosis and management of their patients,” said Patrick W. Serruys, M.D., Ph.D., professor of interventional cardiology at the Thoraxcenter, Erasmus University Hospital, Rotterdam, Netherlands. This impressive multimodality system provides an IVUS image of the vessel while simultaneously performing spectroscopic analysis for the accurate and immediate detection of lipid core plaques demonstrated to complicate stenting and suspected to cause most heart attacks. The Thoraxcenter is proud of its association with InfraReDx and the role we have played in the development of the LipiScan IVUS system and imaging catheter.”

#### **About InfraReDx, Inc.**

InfraReDx, Inc. is a privately funded medical device company improving patient care through the development and commercialization of intelligent imaging technologies to improve the diagnosis and treatment of coronary artery disease. InfraReDx’s LipiScan™ IVUS Coronary Imaging System includes the first and only available catheter to combine both near-infrared spectroscopy (NIR) and intravascular ultrasound (IVUS) technologies to both visualize and characterize the intracoronary lipid core plaques



demonstrated to complicate stenting and suspected of causing the majority of heart attacks. Founded in 1998, InfraReDx is headquartered in Burlington, Massachusetts. For more information, visit [www.infraredx.com](http://www.infraredx.com).

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