

Infraredx Announces Launch of Makoto™ Intravascular Imaging System and Dualpro™ IVUS+NIRS Catheter in Japan

Nipro Vascular Company Brings the First Dual-Modality Intravascular Imaging System and Catheter to the World's Largest Imaging Market

BURLINGTON, Mass., July 31, 2018 -- Infraredx, Inc., a pioneer in intravascular imaging for mapping coronary artery disease, today announced the Makoto™ Intravascular Imaging System, and accompanying Dualpro™ intravascular ultrasound and near-infrared spectroscopy (IVUS+NIRS) catheter, is now available in Japan. The launch follows a successful Spring 2018 limited market release, which included more than 10 hospitals in Japan.

“Infraredx is proud to announce the release of the Makoto Intravascular Imaging System and Dualpro IVUS+NIRS catheter in Japan, the world’s largest imaging market,” said Jason Bottiglieri, President and CEO, Infraredx. “IVUS+NIRS technology has the potential to dramatically change the field of interventional cardiology. Two unique modalities in one catheter provide cardiologists twice the information of other imaging catheters, helping to inform personalized treatment decisions. We thank our parent company Nipro for its significant role in advancing our commitment to the diagnosis and management of coronary artery disease.”

The Makoto Intravascular Imaging System and Dualpro catheter is the only technology on the market to identify vessel structure and plaque composition using IVUS+NIRS. Its launch follows market approval from Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) in August 2017.

“In Japan, we rely heavily on intravascular imaging during percutaneous coronary intervention; so much so that it has become the standard of care, with approximately 90 percent of angioplasty procedures employing intravascular imaging,” said Takashi Kubo, MD, PhD., Wakayama Medical University. “The Makoto Imaging System and Dualpro catheter is the next generation of imaging technology, providing superior deliverability and lesion crossing ability as well as best-in-class image resolution to easily identify the degree of stenosis and plaque burden.”

Dualpro is the only imaging catheter on the market equipped with extended bandwidth IVUS technology. By emitting and carefully processing a broad band of frequencies, the Dualpro IVUS provides best-in-class image resolution without compromising depth of field. Data collected from the NIRS technology are translated into a Chemogram, an easy-to-interpret, color-coded map to identify lipid core plaque (LCP), which can help distinguish between stable plaque and dangerous LCP. Coupled together, IVUS+NIRS arms cardiologists with unparalleled insights into the role LCP plays in heart disease.

There are several global landmark studies, including the Lipid-Rich Plaque (LRP) Study, currently underway, which underscore the importance of identifying LCP for the prediction, and ultimately prevention, of serious heart attacks. Results of the prospective, multi-center LRP Study, along with a U.S. market launch of the Makoto Imaging System and Dualpro IVUS+NIRS catheter, are anticipated in 2H 2018. The technology is currently the only FDA-cleared dual-modality catheter and imaging system indicated for the detection of LCP.

About the Makoto™ Intravascular Imaging System

The Makoto™ Intravascular Imaging System, with accompanying Dualpro™ IVUS+NIRS catheter, is the only technology on the market to identify vessel structure and plaque composition using IVUS+NIRS. Combining best-in-class image resolution with insight into the composition of plaque via Chemogram, IVUS+NIRS provides cardiologists with the tools needed to potentially predict, and ultimately prevent serious heart attacks.

About Infraredx, Inc.

Infraredx, Inc., a Nipro company, is advancing the diagnosis and management of coronary artery disease by providing cardiologists with the most precise imaging tools required to predict and ultimately prevent heart attacks. Its Makoto™ Intravascular Imaging System, with accompanying Dualpro™ IVUS+NIRS catheter, is the only technology on the market to identify the arterial composition and structure using IVUS+NIRS. Infraredx is dedicated to advancing this important field of research and conducting landmark clinical trials to transform how we view and treat heart disease. For more information, please visit www.infraredx.com and connect with Infraredx on [Twitter](#) and [LinkedIn](#).

###

Contacts:

Kaitlyn Dmyterko

Infraredx

kdmyterko@infraredx.com

781-345-9634

Nozomu Fujita

Infraredx

nfujita@infraredx.com

781-345-9480

Lisa Rivero

JPA Health Communications

lrivero@jpa.com

617-657-1305

+++