Teleflex Announces First Patient Enrollment in CTO-PCI IDE Study

June 2, 2020

Study Will Evaluate the Performance of Teleflex Coronary Guidewires and Specialty Catheters in Patients Undergoing Chronic Total Occlusion Percutaneous Coronary Interventions

WAYNE, Pa., June 02, 2020 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX), a leading global provider of medical technologies, today announced the first patient enrollment in a clinical study that will evaluate the performance of Teleflex coronary guidewires and specialty catheters in Chronic Total Occlusion (CTO) percutaneous coronary intervention (PCI) procedures, which is currently an investigational indication for these products. Enrolling up to 150 patients across approximately 15 investigational sites in the US, the CTO-PCI Study is a prospective, single-arm IDE study employing the primary angiographic endpoint of successful (intralumenal) guidewire placement beyond the CTO.

CTOs are longstanding complete blockages in coronary arteries that usually result in profound regional reduction of coronary blood flow (ischemia). Clinically significant CTOs are found in nearly 20% of patients undergoing diagnostic coronary angiography for suspected ischemic heart disease.[1] Often a source of limiting symptoms, CTOs may also contribute to cardiac dysfunction and are associated with poor prognosis.[2]

The principal investigators of the study include David E. Kandzari, MD, Director, Interventional Cardiology and Chief Scientific Officer at Piedmont Heart Institute, Atlanta, GA, and Dimitrios Karmpaliotis, MD, Director of CTO, Complex and High-Risk PCI at Columbia University Irving Medical Center. “We’re excited to embark on the Teleflex CTO study,” said Dr. Kandzari. “We expect the study results to inform contemporary technique in CTO revascularization—a lesion complexity that has long been recognized as the most challenging in interventional cardiology.”

In addition to measuring procedure success and the absence of major adverse cardiac events (MACE), the study will evaluate the frequency of successful recanalization, frequency of MACE in-hospital and at 30 days post-procedure, frequency of clinically significant perforation, procedural success according to crossing technique, and technical success (defined as successful guidewire recanalization using Teleflex study devices).

Study devices include the GuideLiner® V3 catheter, TrapLiner® catheter, Turnpike® catheter, and a series of five coronary guidewires (Spectre™ Guidewire, R350™ Guidewire, Raider™ Guidewire, Warrior™ Guidewire and Bandit™ Guidewire). Each study device is currently commercially available in the US under a more general indication. These products are investigational devices for clinical evaluation as used in the CTO-PCI study.

“The CTO-PCI study, led by Drs. Kandzari and Karmpaliotis, will evaluate the performance of the entire range of Teleflex complex PCI products in the most demanding PCI environment: chronic occlusive coronary disease,” said Teleflex Medical Director, Chris Buller, MD. “The resourcing of this study by Teleflex reflects our commitment to providing the most advanced tools for our customers and their patients.”

About Teleflex Incorporated

Teleflex is a global provider of medical technologies designed to improve the health and quality of people’s lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the

fields of vascular access, interventional cardiology and radiology, anesthesia, emergency medicine, surgical, urology and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rusch®, UroLift®, and Weck® – trusted brands united by a common sense of purpose.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

References:

1. Fefer, P. et al. Current Perspectives on Coronary Chronic Total Occlusions: The Canadian Multicenter Chronic Total Occlusions CTO Registry. *Journal of the American College of Cardiology* 2012;59 (11): 991-7.

2. Tajstra, P. et al. Impact of Chronic Total Occlusion of the Coronary Artery on Long-Term Prognosis in Patients With Ischemic Systolic Heart Failure: Insights From the COMMIT-HF Registry. *JACC: Cardiovascular Interventions* 2016; 9 (17): 1790-97.

Source:

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