



NeoTract Announces Japanese Regulatory Approval for UroLift® System for Treatment of Enlarged Prostate

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WAYNE, Penn.--(BUSINESS WIRE)--Nov. 5, 2018-- NeoTract, a wholly owned subsidiary of Teleflex Incorporated (NYSE:TFX) focused on addressing unmet needs in the field of urology, today announced the Company has received Shonin approval from the Ministry of Health, Labor and Welfare (MHLW) in Japan for the UroLift® System for the treatment of benign prostatic hyperplasia (BPH).

BPH is a common condition marked by bothersome urinary symptoms that can cause loss of productivity, depression, interrupted sleep, and decreased quality of life. If BPH is left untreated, the condition can worsen over time and cause permanent bladder damage. The Company estimates there are about 2.3 million men age 50 and older in Japan who have been diagnosed with BPH¹.

"This regulatory approval is another major milestone for NeoTract, which will allow us to bring the breakthrough UroLift System as a new option to physicians treating the millions of men in Japan experiencing the symptoms of BPH," said Dave Amerson, president of the Teleflex Interventional Urology business unit. "We are pleased that the UroLift System has been adopted as a standard-of-care therapy in the United States and Europe. As in these other markets, our initial efforts in Japan will focus on establishing reimbursement to support widespread adoption."

NeoTract plans to focus on establishing reimbursement over the next 12-18 months, followed by a launch of the UroLift System in select academic medical centers to build strong initial clinical experiences, followed by a full commercial launch. The Company will also enroll a PMDA-mandated post-market clinical study to expand NeoTract's already robust clinical data on the efficacy of the UroLift System, as well as support widespread and rapid adoption of the UroLift System in Japan over the long term.

About the UroLift System

The FDA-cleared UroLift System is a proven, minimally invasive technology for treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The UroLift permanent implants, delivered during a minimally invasive transurethral outpatient procedure, relieve prostate obstruction and open the urethra directly without cutting, heating, or removing prostate tissue. Clinical data from a pivotal 206-patient randomized controlled study showed that patients with enlarged prostate receiving UroLift implants reported rapid and durable symptomatic and urinary flow rate improvement without compromising sexual function. Patients also experienced a significant improvement in quality of life. Over 80,000 men have been treated with the UroLift System in the U.S. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure. The UroLift System Prostatic Urethral Lift procedure is recommended for the treatment of BPH in both the American Urological Association and European Association of Urology clinical guidelines. The UroLift System is available in the U.S., Europe, Australia, Canada, Mexico and South Korea. Learn more at www.UroLift.com.

About NeoTract | Teleflex Interventional Urology

A wholly owned subsidiary of Teleflex Incorporated, the Teleflex Interventional Urology Business Unit is dedicated to developing innovative, minimally invasive and clinically effective devices that address unmet needs in the field of urology. Our initial focus is on improving the standard of care for patients with BPH using the UroLift System, a minimally invasive permanent implant system that treats symptoms while preserving normal sexual function. Learn more at www.NeoTract.com.

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 and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine 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 www.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.

1 : NeoTract|Teleflex market estimates for Japan 2018

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