Research Reinforcing the Effectiveness and Safety of the UroLift® System in the Real-World Setting Presented at 50th Annual ICS Meeting

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New Findings Show UroLift System Same-Day Outpatient Procedure Demonstrates Symptom Improvement for Benign Prostatic Hyperplasia

WAYNE, Pa., Nov. 19, 2020 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX) today announced the results of four studies that were accepted at the ICS 2020 Annual Meeting – Online reinforcing the safety and efficacy of the UroLift® System for the treatment of benign prostatic hyperplasia (BPH).

“BPH commonly causes bothersome urinary symptoms that can affect quality of life. With over 40% of men over the age 50 living with BPH, [1] the robust data presented at ICS highlight the advantages of the UroLift System as a preferred treatment option for many men suffering needlessly from BPH symptoms,” said Dave Amerson, president of the Teleflex Interventional Urology business unit.

“Prostatic Urethral Lift, or PUL, using the UroLift System is an effective and durable treatment for BPH, and a frequent recommendation to my patients who experience difficulties voiding as a direct symptom of BPH,” said Thomas Mueller [+], M.D., New Jersey Urology. “The enlarged prostate presses on and can block the urethra, causing bothersome urinary symptoms. The results of PUL studies presented at ICS indicate that it is a safe and effective option for men with BPH.”

Dr. Mueller’s oral presentation, *Results from the Large Real-World Study of the Prostatic Urethral Lift (PUL) Demonstrate Consistent Safety and Effectiveness for BPH Patients,* was a recipient of the Best In Category Prize for Male Lower Urinary Tract Symptoms (LUTS). The clinical research was designed to expand upon the growing body of evidence of the effectiveness, safety and symptomatic relief of PUL for BPH in a real-world retrospective study. This was the largest real-world investigation of PUL, with male participants averaging 70 years old. Results confirmed that PUL can be offered to a wide patient population in a real-world setting while maintaining the symptomatic improvement and safety profile observed in the pivotal LIFT trial.

UroLift System treatment efficacy was further confirmed in the real-world setting with *Parallel Outcomes of the Prostatic Urethral Lift from Two Distinct Multicenter Real-World Studies*, presented by Karl-Dietrich Sievert[+], M.D., Klinikum Lippe, Detmold Germany. Two published real-world studies, the German Multicenter Retrospective Study and the Large Real-World Retrospective Study, of PUL were compared to assess UroLift System performance. In non-retention subjects, symptom response, quality of life (QoL), and Qmax outcomes were largely consistent between the two real-world studies. Catheter-independence rates of retention subjects were also equivalent, with 86% independence in the German Multicenter Retrospective Study and 87% independence in the Real-World Retrospective Study.

Prostatic Urethral Lift (PUL) Can Reduce Voiding Bladder Pressure Demonstrated by Penile Cuff Test was presented by Brian Mazzarella[+], M.D., of Midtown Urology. This was the first study to evaluate real-world penile cuff testing (PCT) outcomes in men with BPH before and after PUL. Outcomes in International Prostate Symptom Score (IPSS) (p=0.03), QoL (p=0.2) and flow improvement (p=0.1) improved significantly at three months. Using PCT, researchers demonstrated that penile cuff pressure measurements improved by 16% three months after PUL (p=0.07), and 44% of subjects moved out of the obstructed flow category.

The Mechanism of Action of the Uniquely Designed Prostatic Urethral Lift Implant was authored by Daniel Rukstalis[+], M.D., Prisma USC Division of Urology. This study evaluated the short-term and long-term mechanisms of action of PUL using the UroLift System implant. Twenty-four canines who underwent PUL were evaluated for histopathology. Resected prostate tissue from human subjects was also analyzed to provide further insight into the previously seen symptomatic improvements in humans treated with PUL. The results of the study show that the UroLift System immediately causes localized compression, and sustained pressure by implants results in subsequent tissue remodeling and scarring which contributes to durability of symptom relief.

About the UroLift® System

The UroLift® System is a minimally invasive treatment for lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). It is indicated for the treatment of symptoms of an enlarged prostate up to 100cc in men 45* years or older (*50 years outside US). The UroLift permanent implants, delivered during an outpatient procedure, relieve prostate obstruction without cutting, heating, or removing prostate tissue. The UroLift System is the only leading BPH procedure shown to not cause new onset, sustained erectile or ejaculatory dysfunction in the L.I.F.T. pivotal study.*[2-5] Most common adverse events are temporary and can include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.[2] Rare side effects, including bleeding and infection, may lead to a serious outcome and may require intervention. As with any medical procedure, individual results may vary. Consult the Instructions for Use (IFU) for more information. The Prostatic Urethral Lift procedure (using the UroLift System) is recommended for the treatment of BPH in both the American Urological Association and European Association of Urology clinical guidelines. 200,000 men have been treated with the UroLift System in select markets worldwide.† Learn more at www.UroLift.com.

About Teleflex Interventional Urology

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 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 sexual function.*[2,4,5] 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.

+Dr. Thomas Mueller, Dr. Karl-Dietrich Sievert, Dr. Brian Mazzarella and Dr. Daniel Rukstalis are paid consultants of NeoTract | Teleflex Interventional Urology

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1. Berry, S.J., et al., The Development of Human Benign Prostatic Hyperplasia with Age, J Urology 1984; 132: 474-479
2. Roehrborn, J Urology 2013 LIFT Study
3. Roehrborn, Can J Urol 2017 5 Year LIFT Study
4. AUA BPH Guidelines 2003, 2020
5. McVary, J Sex Med 2016

*No instances of new, sustained erectile or ejaculatory dysfunction in the L.I.F.T. pivotal study
† Management estimate based on product sales and average units per procedure

Contacts:
For Teleflex Incorporated:
Jake Elguicze, 610.948.2836
Treasurer and Vice President, Investor Relations

Media:
Nicole Osmer, 650.454.0504
nicole@healthandcommerce.com

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