



Teleflex Announces Positive Data Emphasizing the Effectiveness of the UroLift® System Treatment for Enlarged Prostate Across Broad Patient Populations

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Data Presented at European Association of Urology Highlights Safety and Versatility of the Minimally Invasive UroLift System in a Real-World Setting

WAYNE, Pa., July 21, 2020 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX) today announced that data from three studies of the UroLift® System were presented at the European Association of Urology (EAU) 2020 virtual congress, underscoring the safety and effectiveness of the minimally invasive treatment for benign prostatic hyperplasia (BPH) among broad patient groups.

"The UroLift System is a standard of care treatment that provides rapid symptom relief and recovery for patients suffering from the burdensome symptoms of BPH,"¹ said Dave Amerson, president of Teleflex Interventional Urology business unit. "Results from these studies are largely consistent with those found in previous clinical studies of the UroLift System, further supporting the safety and lasting benefits of this minimally invasive treatment in the real-world and among difficult-to-treat patient populations."

Oliver Kayes, M.D.,* Leeds Teaching Hospitals NHS Trust, presented *Prostatic Urethral Lift Real-World Study Confirms Effectiveness and Safety in a Broad Array of Patient Groups*. The study highlighted real-world results of 3,226 patients treated with the UroLift System across 22 sites in the U.S., UK and Australia. Outcomes were analyzed from patients with urinary retention, large prostate volume (≥ 80 g), obstructive median lobe (OML), and prior radiation for prostate cancer, as well as non-urinary retention patients, at one-month, three-month, six-month, one-year and two-year timepoints.

Data from the study showed significant improvement in International Prostate Symptom Score (IPSS) at all time points for non-urinary retention patients following treatment with the UroLift System and are generally consistent with randomized clinical studies. Additionally, patients not seen typically in randomized clinical studies, such as those with mild to moderate symptoms ($n = 496$), large prostate volume ($n = 85$), obstructive median lobes ($n = 277$) and those who received prior radiation for prostate cancer ($n = 82$) experienced symptomatic improvement. Findings from the study also showed that OML patients experienced significant relief after treatment, with an average 46% improvement in IPSS at the three-month timepoint.

"This is the largest and most comprehensive real-world investigation of a minimally invasive treatment for enlarged prostate, with results reaffirming those seen in controlled studies of the UroLift System," said Mr. Kayes. "Additionally, these data indicate that the UroLift System provides rapid symptom relief to a wide range of patient cohorts without affecting safety outcomes."

A presentation entitled *12-month symptom and urodynamic outcomes of the prostatic urethral lift in patients with acute urinary retention (PULSAR)* was presented by Mark Rochester,* M.D., Norwich & Norfolk University Hospital. The study examined the feasibility of the UroLift System to treat patients with acute urinary retention.

Results from the study showed that patients experienced symptom relief at all time points following treatment with the UroLift System. Absolute IPSS scores were consistent with the pivotal L.I.F.T study, and quality of life outcomes were significantly better at the six and 12-month timepoints following treatment. Of the 52 patients included in the study, 60% were catheter-free by one month, and 73% by six months through study end. Additionally, 82% of patients were able to stop treatment with alpha blockers following treatment with the UroLift System and 87.5% of patients returned to normal activities 8.5 days after treatment. Results also demonstrated an improvement in urodynamic measurements among patients treated with the UroLift System, with a 38% reduction in Bladder Outlet Obstruction Index (BOOI). Finally, 83% of patients reported that they would recommend the procedure.

"The results from this study contribute to the robust portfolio of clinical evidence supporting the UroLift System treatment for patient subgroups that are not commonly seen in clinical trials," said Mr. Rochester. "These findings highlight the safety and effectiveness of the UroLift System in treating men with acute urinary retention, offering this challenging patient population a viable alternative to long-term catheter management and major surgery."

A third study — *Meta-analysis comparison of sexual function outcomes after treatment with prostatic urethral lift or medical therapy*—was presented by Claus Roehrborn,* M.D., University of Texas Southwestern Medical Center. Results from the analysis showed that patients treated with the UroLift System experienced significant improvements in ejaculatory function and erectile function through at least 24 months following treatment, while patients in some medical therapy groups did not experience significant average improvement at any timepoint.

"Data presented at the EAU meeting is an important reminder that the UroLift System can be a solution for BPH patients and urologists facing huge waiting lists driven by the pause in elective surgeries due to COVID-19. Urologists can offer the UroLift System in an outpatient setting, providing relief to their patients without unnecessary delays," said Matthew Wiggins, General Manager, EMEA, Teleflex. "Furthermore, the data shows that the UroLift System is an effective treatment for patients in urinary retention, who, according to current EAU guidance in the COVID-19 era, should be prioritized due to their significant risks of complications."²

About the UroLift® System

The UroLift System is a proven, minimally invasive technology for treating 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. 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.^{1,3,4} Most common adverse events are temporary and can include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence.¹ 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. More than 175,000 men have been treated with the UroLift System in select markets worldwide.*** As with any medical procedure, individual results may vary. 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.**^{5,6} 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.

*Mr. Oliver Kayes, Mr. Mark Rochester and Dr. Claus Roehrborn are paid consultants of NeoTract | Teleflex Interventional Urology.

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¹ Roehrborn, J Urology 2013 LIFT Study

² European Association of Urology. EAU Guidelines Office Rapid Reaction Group:

An organisation-wide collaborative effort to adapt the EAU guidelines recommendations to the COVID era <https://uroweb.org/guideline/covid-19-recommendations/>

³ AUA BPH Guidelines 2003, 2010, 2018

⁴ McVary, J Sex Med 2014

⁵ Shore, Can J Urol 2014 Local Study

⁶ Speakman et al. 2014 BJUI International

** No instances of new, sustained erectile or ejaculatory dysfunction

***Management estimate based on product sales and average units per procedure

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Source: Teleflex Incorporated