NeoTract Announces Positive Guidelines from European Association of Urology for Minimally Invasive Treatment for Benign Prostatic Hyperplasia

UroLift System Recognized for High Level of Clinical Evidence

PLEASANTON, Calif. – April 30, 2015– NeoTract, Inc., a medical device company focused on addressing unmet needs in the field of urology, today announced that the European Association of Urology (EAU) has given the UroLift® System a positive recommendation for the treatment of patients with benign prostatic hyperplasia (BPH) in its newly updated “Guidelines for the Management of Non-Neurogenic Male Lower Urinary Tract Symptoms, Including Benign Prostatic Obstruction,” published in European Urology.

The guidelines assist practicing urologists in Europe in making informed decisions based on the highest-quality scientific data. The guidelines and recommendations were based on a rigorous systematic review of the published literature on the UroLift System, performed by a panel of experts with urological and epidemiological backgrounds.

The review panel graded the clinical evidence supporting the UroLift device Level 1-b, the second-highest level of evidence, denoting evidence obtained from at least one properly designed randomized controlled trial that suggests that the benefits of the clinical service outweigh the potential risks.

“We are pleased that the European Association of Urology has recognized the UroLift System as a treatment option for patients suffering from an enlarged prostate – an extremely common men’s condition that greatly impacts quality of life,” said Dave Amerson, president and CEO of NeoTract. “This positive recommendation is another testament to the rigor and excellence of the body of clinical data that supports the use of the UroLift System, which involves no cutting, heating or removal of tissue, and is the only treatment option providing total preservation of sexual function. We look forward to reporting the latest clinical trial results from the UroLift System next month.”

Three-year results of the L.I.F.T. IDE Study, a multi-center, randomized, blinded U.S. clinical trial, as well as one-year results from the randomized BPH-6 European multi-center randomized study comparing UroLift to transurethral resection of the prostate (TURP), will be presented at the American Urological Association’s annual conference taking place May 15-19 in New Orleans.

The UroLift device has received regulatory clearance in the US, is CE marked in Europe, and is currently available in Denmark, Finland, France, Germany, Italy, The Netherlands, Norway, Spain, Sweden, Turkey and the United Kingdom.

About the UroLift System

The UroLift System is a novel, minimally invasive technology for treating lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The UroLift permanent implants, which can be 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. 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 is available in the U.S., Europe, Australia and Canada. Learn more at www.UroLift.com.
About Benign Prostatic Hyperplasia (BPH)
BPH, also known as enlarged prostate, is a medical condition in which the prostate gland that surrounds the male urethra becomes enlarged with advancing age and begins to obstruct the urinary system. The condition is common, affecting approximately 37 million men in the United States alone. BPH symptoms include sleepless nights and urinary problems, and can cause loss of productivity, depression and decreased quality of life. About one in four men experience BPH-related symptoms by age 55 and by age 70, over 80 percent of men suffer from BPH.

Medication is often the first-line therapy for enlarged prostate, but relief can be inadequate and temporary. Side effects of treatment can include sexual dysfunction, dizziness and headaches, prompting many patients to quit using the drugs. For these patients, the classic alternative is surgery that cuts or ablates prostate tissue to open the blocked urethra. While current surgical options, such as transurethral resection of the prostate (TURP), can be very effective in relieving symptoms, it can also leave patients with permanent side effects such as urinary incontinence, erectile dysfunction and retrograde ejaculation (dry orgasm).

About NeoTract
NeoTract, Inc. is dedicated to developing innovative, minimally invasive and clinically effective devices that address unmet needs in the field of urology. The company’s 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.

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