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NxThera Announces Presentation of Two-Year Outcomes Data for Its Minimally Invasive Rezūm® System for Enlarged Prostate Treatment at the 2017 American Urological Association Annual Meeting

Two-Year Data from Rezūm II Pivotal Study Demonstrate Significant and Durable Lower Urinary Tract Symptom Relief and Preserved Sexual Function After Treatment with Rezūm System

MAPLE GROVE, MINN. (May 15, 2017) — NxThera, Inc., a medical device company pioneering the application of its convective radiofrequency thermotherapy platform to treat endourological conditions, announced the two-year outcomes data from the Rezūm II pivotal clinical trial of its minimally invasive Rezūm® System to treat lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH) at the 2017 American Urological Association (AUA) annual meeting in Boston.

The abstract, entitled, “Convective radiofrequency thermal therapy: durable two-year outcomes of a randomized controlled and prospective crossover study to relieve lower urinary tract symptoms due to benign prostatic hyperplasia,” was presented by Dr. Claus Roehrborn, co-principal investigator and professor and chair, Division of Urology at University of Texas Southwestern Medical Center. Dr. Roehrborn reported significant LUTS relief that remained durable at two years after treatment with the Rezūm System, which can be performed in an office or outpatient setting. The results are published in the June issue of The Journal of Urology.

“The two-year data confirms that Rezūm is an effective, durable treatment option and should be considered a first-line therapeutic alternative to medical therapy for men seeking treatment for bothersome moderate to severe symptoms of BPH including those with median lobe hyperplasia,” Dr. Roehrborn said.

BPH is one of the top 10 most common and costly conditions affecting 12 million American men aged 50 or older, with nearly 800,000 newly diagnosed each year. BPH causes significant quality of life issues including waking up multiple times during the night to urinate, frequency, urgency, irregular and weak urinary flow, anxiety, challenges with sexual function and limitation in daily activities. The Rezūm System uses radiofrequency current to create thermal energy that is convectively delivered to obstructive prostate tissue through targeted, precise treatments. The treated tissue is then resorbed by the body’s immune system which alleviates the symptoms of BPH and improves patients’ quality of life and ability to urinate, while preserving sexual function.

In addition to the obstructive tissue in the lateral lobes or transition zone of the prostate, two-of-three men diagnosed with BPH also have obstructive tissue under the floor of the urethra in the central zone of the prostate which requires treatment. The clinical data from the Rezūm pivotal study demonstrates that urologists can use the Rezūm System to effectively treat obstructive prostate tissue in either region.

The Rezūm II randomized, controlled trial enrolled 197 patients across 15 centers in the United States, and one and two-year data from this trial has demonstrated durable symptom reduction and preserved sexual function in patients who were treated with the Rezūm System. In addition, of the 61 patients in the
control arm of the study, 53 elected and qualified to cross over and receive a treatment with the Rezūm System. Key findings of this study include:

- Clinically significant and durable improvement in urinary symptoms through two years, as measured by a decrease in International Prostate Symptom Score (IPSS) of 11.2 points (-51 percent).
- Clinically significant and durable improvement in urinary flow rate (Qmax) of +6.2 mL/sec (increase of 68 percent) at three months that remained significantly improved at two years.
- For the 75 percent of patients in this study who had severe LUTS (a baseline IPSS ≥19), IPSS improvement was -13.0 points at two years.
- Without exception, the seven individual IPSS domains, including urgency and nocturia, reflected the significant relief of symptoms over two years, p<0.0001.
- Overactive bladder bother and impact on quality of life improved significantly through two years, p<0.0001.
- ICS male incontinence scores improved significantly through two years, p<0.0001.
- Median lobe treatments were performed in 58 of 188 (31 percent) patients in both arms of the trial; those with and without median lobe treatments achieved similar improvements in both IPSS and Qmax.
- Sexual function was preserved in patients treated with the Rezūm System, as measured via the International Index of Erectile Function (IIEF-15) and Male Sexual Health Questionnaire (MSHQ).

“This two-year data from Rezūm II pivotal trial clearly demonstrates compelling durable clinical outcomes that provide urologists with an effective and minimally invasive treatment option that provide their patients who may have been watchfully waiting, or treating LUTS with medication with sustained relief from the symptoms of BPH,” said Bob Paulson, president and CEO of NxThera. “The Rezūm System can be used to efficiently and effectively treat the enlarged prostate tissue both lateral to and under the floor of the urethra that obstructs urinary flow and causes the bothersome symptoms of BPH, allowing urologists to optimize the treatment approach based on their patients’ individual anatomy. Rezūm is transforming the BPH treatment experience for urologists and their patients suffering from BPH by providing a versatile, in-office or outpatient treatment option for men interested in nonsurgical and non-medication alternatives to treat BPH and resume their quality of life.”


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About NxThera

NxThera pioneered its convective radiofrequency thermotherapy platform technology to treat a variety of endourological conditions, beginning with BPH. The company is furthering the application of its technology platform through advanced research and development, and clinical studies, targeting the treatment of prostate cancer and kidney cancer. NxThera’s FDA-cleared Rezūm System to treat BPH is a next-generation transurethral needle ablation system that uses radiofrequency to create thermal energy that is convectively delivered to obstructive prostate tissue in targeted, precise treatments, with minimal discomfort. Treatments with the Rezūm System improve the bothersome symptoms of BPH, including urine flow and quality of life. Founded in 2008, NxThera is located in Maple Grove, Minn. For more information, visit www.Rezūm.com.