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**NXThERA RECEIVES 510(K) CLEARANCE FOR REZUM SYSTEM TO IMPROVE LIVES OF MEN SUFFERING FROM SYMPTOMS ASSOCIATED WITH BENIGN PROSTATE HYPERPLASIA (BPH)**

***Transforming the BPH treatment experience for patients and urologists***

Maple Grove, Minn. – September 2, 2015 -- [NxThera, Inc.](#), a medical device company pioneering the application of its Convective Water Vapor Energy (WAVE™) platform technology to treat endourological conditions, is pleased to announce it has received FDA 510(k) clearance of the company's Rezūm® System to treat BPH.

"The clinical data from the Rezūm II randomized, controlled clinical study demonstrated clinically and statistically significant BPH symptom improvement in as little as two weeks, as well as meaningful improvements in the quality of life for patients," said Dr. Kevin T. McVary, Professor and Chair, Division of Urology at Southern Illinois University School of Medicine. "The Rezūm therapy is performed in an office setting without the need for general anesthesia, while demonstrating minimal complications and preserving sexual function."

It is estimated that more than 12 million American men suffer from BPH with over 750,000 new cases diagnosed each year. Currently 50% of these men struggle to deal with the symptoms of BPH, including frequency, nocturia, intermittency, urgency, weak stream and straining to urinate as a result of being refractory or non-responsive, or unwilling to deal with the side effects of medical therapy, or reluctant to undergo an invasive surgical procedure requiring general anesthesia. The Rezūm procedure is an effective, safe and minimally invasive BPH treatment option that gives urologists the opportunity to offer an office-based or outpatient treatment option that may provide relief to men who are looking for an alternative to currently available BPH treatment offerings.

The Rezūm System uses radiofrequency energy to transform sterile water into stored thermal energy in the form of vapor, or steam. This water vapor is convectively delivered directly into the obstructive prostate tissue that causes BPH, where condensation releases enough thermal energy to gently and immediately denature the targeted prostate tissue cells to cause necrosis. The treated tissue is absorbed by the body's natural immune system.

"We are very pleased Chesapeake Urology Associates and our own Dr. Richard Levin had the opportunity to play an important role in evaluating this innovative WAVE technology to treat BPH as part of the Rezūm II clinical study. When BPH patients present in our offices, they typically are looking for treatment options in addition to medical management and surgery. Today's FDA decision is welcome news for patients and their urologists to discuss and consider the Rezūm procedure as a new treatment option in the BPH clinical continuum of care," said Dr. Sanford J. Siegel, President & CEO of Chesapeake Urology Associates.



“FDA clearance of our Rezūm System to treat BPH is a significant milestone for NxThera and our team of dedicated and passionate employees, and a testament to the vision and commitment of our many clinical advisors, clinical study investigators, investors, and our founder and Chief Technology Officer Michael Hoey,” shared J. Robert Paulson, President and CEO of NxThera. “We now will shift our focus to accelerating and expanding access to and adoption of the Rezūm procedure in the U.S. during early 2016, and expanding into key international markets later in the year. We will support this commercial expansion by providing world-class clinical training and education programs to urologists and their practices who are committed to expanding the BPH treatment options they offer to meet the needs of their diagnosed but untreated patients.”

### **About NxThera**

NxThera has pioneered its Convective Water Vapor Energy (WAVE™) technology platform to treat a variety of endourological conditions beginning with BPH, and including prostate cancer and kidney cancer. NxThera’s Rezūm System to treat BPH uses radiofrequency energy to create sterile water vapor, or steam, to convectively deliver targeted, precise thermal energy treatments in a simple, office-based or hospital procedure with minimal discomfort, and provide improvements in urine flow and quality of life. Founded in 2008, NxThera is located in Maple Grove, Minnesota.