Five-Year Data from the WATER II Study Demonstrate Aquablation Therapy Delivers Significant Durable Improvement of Benign Prostatic Hyperplasia Symptoms while Preserving Sexual Function in Men with Large Prostates

April 28, 2023

- 5-Year results from WATER II when combined with 5-year results from the original WATER study demonstrate that Aquablation therapy provides long-term symptom relief while preserving sexual function for patients with small and large prostates.
- The study concluded that Aquablation therapy:
  - Is safe, effective and durable with symptoms metrics demonstrating large immediate and sustained improvements for patients
  - 96.3% of patients based on Kaplan-Meier analysis avoided a secondary intervention due to recurrent symptoms at five years

REDWOOD CITY, Calif., April 28, 2023 (GLOBE NEWSWIRE) -- PROCEPT® BioRobotics Corporation today announced that 5-year results from the WATER II Study demonstrate that Aquablation therapy, a minimally invasive, robotic, surgical treatment for benign prostatic hyperplasia (BPH), safely and effectively provides durable symptom relief and preserves sexual function out to five years for men with large prostates (80 – 150mL). The study, published in this month's *Journal of Urology*, demonstrated that patients continued to experience significant and long-term improvement in their symptoms and quality of life.

The WATER II Study is the first FDA, prospective multicenter study successfully completed for larger prostates. The 5-year results maintained excellent clinical outcomes including a significant reduction in IPSS (mean reduction of 16 points), increase in peak urinary flow rate (Qmax, mean increase of 9.2 ml/sec) and improvement in quality of life (average reduction in IPSS QoL of 3.3). Over five years the trial showed a surgical retreatment rate of only 3.7% based on Kaplan-Meier analysis.

Aquablation therapy proved to provide significant symptom relief for patients over five years while demonstrating no impact on erectile function and minimal impact on ejaculatory function or urinary continence. The WATER II evidence, combined with the prior WATER study comparing Aquablation therapy to the "gold standard" transurethral resection of the prostate (TURP), indicate that Aquablation therapy is the only treatment modality that can effectively treat all prostate glands with minimal impact on sexual function or urinary continence.

"Aquablation therapy now has 5-year results from two pivotal studies that demonstrate the reproducibility of Aquablation therapy to deliver significant symptom relief while preserving sexual function no matter the size of the patient's prostate,"said Sham Shiblaq, EVP and Chief Commercial Officer of PROCEPT BioRobotics. "These results are further validated by the large and growing number of hospitals and surgeons that have adopted Aquablation as their new standard of care for the treatment of BPH."

"The surgical management of BPH has undergone significant change over the past 20 years but most surgical options are limited in one way or another," said Dr. Naeem Bhojani, manuscript lead author. "With real time ultrasound guidance and robotic execution, Aquablation therapy has the potential to treat prostates of nearly any size and this 5-year data validates the durability and reproducibility of the procedure."

About Aquablation Therapy
Aquablation therapy is the first and only image-guided, automated, heat-free robotic therapy for the treatment of BPH. The system's real-time ultrasound imaging provides the surgeon with a multi-dimensional view of the prostate enabling personalized treatment planning tailored to each patient's unique anatomy. The surgeon can specify which areas of the prostate to remove while preserving the anatomy that controls erectile function, ejaculatory function and continence. Once the treatment plan is mapped, the automated robot removes prostate tissue in a precise, targeted, and controlled fashion using novel, heat-free waterjet technology.

This novel technology is backed by numerous peer-reviewed publications demonstrating its safety, efficacy, and the durability of its outcomes. The cornerstone of the data is two, prospective, FDA trials with 5-year data; WATER and WATER II. The WATER study (the U.S. pivotal trial for FDA approval) randomized Aquablation against TURP, which has been the standard of care for resection of prostates smaller than 80mL, in a double-blinded study. The trial demonstrated superior safety and comparable efficacy to TURP in prostates 30ml to 80ml in size and superior safety and efficacy in prostates 50mL to 80mL in size. The WATER II study included men with a prostate size greater than 80ml undergoing Aquablation. The study met its pre-specified performance goal for safety and efficacy. The two, FDA trials with 5-year follow-up have demonstrated consistent results across various prostate anatomy.

About PROCEPT BioRobotics Corporation
PROCEPT BioRobotics is a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. PROCEPT BioRobotics develops, manufactures and sells the AquaBeam Robotic System, an advanced, image-guided, surgical robotic system for use in minimally invasive urologic surgery with an initial focus on treating benign prostatic hyperplasia, or BPH. BPH is the most common prostate disease and impacts approximately 40 million men in the United States. PROCEPT BioRobotics designed Aquablation therapy to deliver effective, safe and durable outcomes for males suffering from lower urinary tract symptoms, or LUTS, due to BPH that are independent of prostate size and shape or surgeon experience. PROCEPT BioRobotics has developed a significant and growing body of clinical evidence, which includes nine clinical studies and over 150 peer-reviewed publications, supporting the benefits and clinical advantages of Aquablation therapy.

Important Safety Information

All surgical treatments have inherent and associated side effects. For a list of potential side effects visit https://aquablation.com/safety-information/.

Investor Contact:
Matt Bacso, CFA
VP, Investor Relations and Business Operations
m.bacso@procept-biorobotics.com