Real-World, Long-Term Data Demonstrate Sustained Benefits of Aquablation Therapy for Men with Benign Prostatic Hyperplasia

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Data from the Icahn School of Medicine at Mount Sinai and Potomac Urology presented at the 2024 AUA Annual Meeting highlight Aquablation therapy's potential to become the new standard of care in BPH for prostates of all sizes

SAN JOSE, Calif., May 06, 2024 (GLOBE NEWSWIRE) -- PROCEPT BioRobotics® Corporation (Nasdaq: PRCT) (the "Company"), a surgical robotics company focused on advancing patient care by developing transformative solutions in urology, today announced long-term, real-world data showcasing the benefits of Aquablation therapy for the treatment of symptomatic benign prostatic hyperplasia (BPH) at both academic and commercial settings. The results were presented this past weekend at the American Urological Association (AUA) Annual Meeting in San Antonio, Texas.

"The data presented at AUA confirm the safety and long-term durability of Aquablation therapy in treating men with symptomatic benign prostatic hyperplasia, regardless of prostate size or shape," said Reza Zadno, CEO of PROCEPT BioRobotics. "The fact that 12 abstracts were presented this past weekend underscores the growing body of real-world evidence to support that Aquablation therapy delivers the highest standard in urological care."

Icahn School of Medicine at Mount Sinai – 4-Year Outcomes
Aquablation therapy was performed on 275 adult men with moderate to severe BPH with a prostate volume between 38 and 293 mL (mean volume of 108.3 mL). The patients were out to 4 years post-procedure.

Key results:

- Mean prostate volume decreased from 108.3 mL to 66.2 mL (-38.9%).
- International Prostate Symptom Score (IPSS) improved from 24.2 at baseline to 7.1 at 4 years.
- Peak urinary flow rate (Qmax) increased nearly 3-fold from 6.1 mL/sec to 17.1 mL/sec.
- Antegrade ejaculation was preserved for 99% of men.
- Surgical retreatment occurred in 1.8% patients.

"BPH is a condition that impacts the majority of men as they age, but treatment options have not historically found the balance between alleviating symptoms from enlarged prostates while preserving sexual function and urinary continence. While there have been studies demonstrating the durable efficacy and safety profile of Aquablation therapy for the treatment of BPH, this is the largest academic single-center experience demonstrating long-term performance in BPH management," said Dr. Steven Kaplan, Icahn School of Medicine at Mount Sinai.

Potomac Urology - Aquablation Case Series of 812 Consecutive Men with LUTS due to BPH
Three surgeons at Potomac Urology collected data on 812 consecutive men treated with Aquablation therapy. Routine procedural characteristics, adverse events, symptom scores and uroflow were collected over 3 years. The data showed that safety has been improved and efficacy was consistent against FDA clinical trials. Day case Aquablation therapy has also been shown to be a viable option.

Key results:

- Mean age, IPSS, Qmax and prostate volume were 69 ± 8, 21 ± 7, 11 ± 6, and 77 ml (range 22-263 ml), respectively.
- IPSS at 8, 12, 24 and 36 months was 7 or less.
- 14% of patients were in preoperative retention with 94% of those patients passing their trial of voids.
- Secondary intervention due to recurrent LUTS was 1.6%.

"Aquablation therapy strikes the ideal balance of providing the efficacy and durability of a resective procedure while providing the safety and tolerability of a minimally invasive procedure. We have treated more than 800 men with Aquablation therapy and feel that the results truly speak for themselves," said Shawn Marhamati, MD, MS, at Potomac Urology.

Registered attendees can access the full list of Aquablation therapy presentations here.
Additional abstract highlights include:

- **MP20-01: WATER vs WATER II 5-Year Update: Comparing Aquablation Therapy for Benign Prostatic Hyperplasia in 30-80 cc and 80-150 cc Prostates**
  Mohamad Baker Berjaoui, MD
  University of Toronto
  This study presented the final analysis comparing clinical trial outcomes of Aquablation to TURP for the treatment of lower urinary tract symptoms (LUTS) in small-to-moderate prostates (WATER study: NCT02505919) to those in large prostates (WATER II: NCT03123250) at five-year follow-up. The final analysis of the two, prospective clinical trials demonstrated that

Aquablation therapy has durable outcomes and low retreatment rates for the treatment of LUTS/BPH independently of prostate volume between 30-150 ml prostates.

- **MP: 20-03: Aquablation Real-World Prostate Size Utilization and Reported Bleeding Events Across 5 Years**
  Dean Elterman, MD, MSc, FRCSC
  University of Toronto
  While clinical studies in the past have evaluated Aquablation therapy's application in glands between 30-150 mL, this study sought to evaluate how the technology is used in the real-world setting. 31,944 procedures were evaluated from 2019-2023 in patients across Asia, Europe and North America. Aquablation showed a consistent adoption in use across a broad range prostates sizes over five years with a very low risk of bleeding.

- **MP20-05: Day Case Aquablation: First Published Experience Report in an Ambulatory Surgical Center (ASC)**
  Kevin C. Zorn, MD, FACS, FRCSC
  BPH Canada Prostate Surgery Institute
  The study investigated the feasibility, safety and efficacy of same day discharge (SDD) after Aquablation specifically in an ASC. Results showed that same day discharge after Aquablation therapy for BPH at an ASC appears to be a safe and effective approach, yielding favorable outcomes in terms of symptom relief and patient satisfaction.

For more information on Aquablation therapy, please visit www.procept-biorobotics.com/aua2024/.

About Aquablation Therapy
Aquablation therapy is the first and only ultrasound guided, robotic-assisted, heat-free waterjet 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 by the surgeon, the predictable robotic-assisted execution enables prostate tissue to be removed in a precise, targeted, and controlled fashion.

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. The Company 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.

Forward-Looking Statements
This release contains forward-looking statements within the meaning of federal securities laws, including with respect to the Company's projected financial performance for full year 2024, statements regarding the potential utilities, values, benefits and advantages of Aquablation® therapy performed using PROCEPT BioRobotics' products, including AquaBeam ® Robotic System, which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware. Forward-looking statements may include statements regarding financial guidance, market opportunity and penetration, the Company's possible or assumed future results of operations, including descriptions of the Company's revenues, gross margin, profitability, operating expenses, installed base growth, commercial momentum, reimbursement coverage, overall business strategy, or information regarding the impact of other global events on the Company and its operations. Forward-looking statements should not be read as a guarantee of future performance or results and may not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These risks and uncertainties are described more fully in the section titled "Risk Factors" in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's annual report on Form 10-K expected to be filed with the SEC on or about February 28, 2024. PROCEPT BioRobotics does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein. These forward-looking statements should not be relied upon as representing PROCEPT BioRobotics' views as of any date subsequent to the date of this press release.

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/.

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