PROCEPT BioRobotics® Advances Prostate Cancer Program with WATER IV Study Enrollment Completion and Expanded IDE Approval

May 28, 2026

SAN JOSE, Calif., May 28, 2026 (GLOBE NEWSWIRE) -- PROCEPT BioRobotics (Nasdaq: PRCT) today announced two milestones in its WATER IV prostate cancer clinical program: completion of enrollment in the randomized WATER IV study evaluating Aquablation® therapy versus radical prostatectomy, and FDA Investigational Device Exemption (IDE) approval for a second randomized protocol evaluating Aquablation therapy versus active surveillance.

The first randomized WATER IV study (WATER IV RP) fully enrolled 280 planned patients and is the only FDA randomized study comparing Aquablation therapy to radical prostatectomy, the established surgical standard of care. Based on current timelines, the Company expects to present the WATER IV RP primary endpoint results at the American Urological Association (AUA) Annual Meeting in spring 2027.

The second randomized study in the WATER IV clinical program (WATER IV AS) will enroll up to 333 patients globally and evaluate Aquablation therapy versus active surveillance in men with Grade Group 1 and 2 prostate cancer. Active surveillance is commonly used for men with lower-risk prostate cancer to avoid the quality-of-life impact associated with radical treatment, although many patients ultimately progress to surgery or radiation over time. WATER IV AS is designed to evaluate whether Aquablation therapy may provide an earlier treatment option for men on active surveillance before the disease progresses further. Patients will be followed for ten years, including biopsy assessment at one year and MRI-based whole gland evaluation at three years.

“We are excited to complete enrollment in the first randomized WATER IV protocol, reflecting strong interest from physician investigators as well as patients in evaluating Aquablation as a new approach to prostate cancer treatment,” said Larry Wood, President and Chief Executive Officer of PROCEPT BioRobotics. “The IDE approval for the additional randomized WATER IV protocol enables us to evaluate whether earlier intervention with Aquablation may offer men on active surveillance a quality-of-life-preserving treatment option rather than waiting for the disease to progress.”

Both randomized WATER IV protocols will follow patients for ten years and are designed to evaluate the long-term experience of men with prostate cancer. The studies will assess both disease control and quality-of-life outcomes over time, including the impact of treatment on urinary, sexual, and overall function. No other prostate cancer therapy has been evaluated with such a level of rigor early in its development, reflecting the company’s continued commitment to advancing science and innovation in prostate care.

For more information on the WATER IV study, please visit: https://clinicaltrials.gov/study/NCT06651632

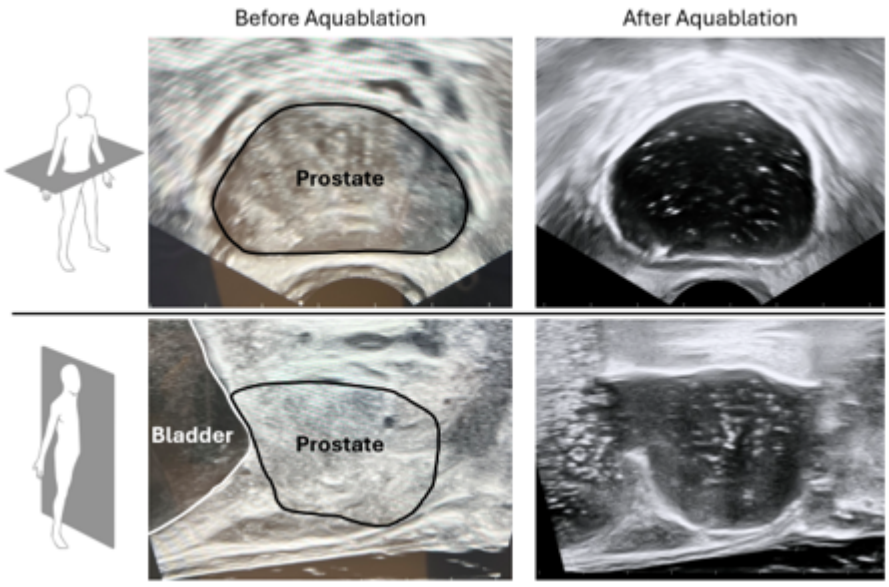

Figure: Aquablation Therapy for Prostate Cancer
Ultrasound-guided, transurethral robotic waterjet resection of the prostate designed to remove cancer, at-risk tissue, and any obstructive tissue resulting in >95% of the gland being resected leaving only the outer prostatic capsule intact.

About PROCEPT BioRobotics® Corporation
PROCEPT BioRobotics is a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. The

Company manufactures the AQUABEAM® and HYDROS® Robotic Systems. The HYDROS Robotic System is the only AI-powered, robotic technology that delivers Aquablation therapy. 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. In addition to its leadership in BPH treatment, the Company is pursuing clinical research initiatives in prostate cancer utilizing investigational applications of its robotic and AI-enabled technologies. BPH is the most common prostate disease and impacts approximately 40 million men in the United States. The Company has developed a significant and growing body of clinical evidence with approximately 250 peer-reviewed publications, supporting the benefits and clinical advantages of Aquablation therapy.

Forward-Looking Statements
This press release may contain forward-looking statements within the meaning of federal securities laws. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those anticipated or implied in such statements. PROCEPT BioRobotics undertakes no obligation to publicly update or revise any forward-looking statements.

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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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/4f4bd11e-cbd0-4365-8b2c-b55a77eb8bdd.