PROCEPT BioRobotics® Receives U.S. FDA Investigational Device Exemption to Investigate Aquablation® Therapy for Prostate Cancer

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REDWOOD CITY, Calif., Sept. 12, 2023 (GLOBE NEWSWIRE) -- PROCEPT BioRobotics Corporation (NASDAQ: PRCT) (“PROCEPT BioRobotics”), a global leader in surgical robotics, announced today the Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to investigate the safety and efficacy of Aquablation therapy for prostate cancer.

The IDE approval allows PROCEPT BioRobotics to initiate a single-arm feasibility study in the United States. The data generated from this IDE study will support future research and regulatory applications in the United States. The study will enroll patients with localized prostate cancer at three prestigious cancer centers, Keck Medical Center of USC, Perlmutter Cancer Center at NYU Langone Health, and Mount Sinai Tisch Cancer Center.

“Aquablation Therapy, recognized for its efficacy and safety in resecting prostate tissue for BPH, offers a potential paradigm shift in how urologists might address localized prostate cancer. The waterjet resection technique has the distinct capability to precisely eradicate prostate tissue, providing the potential of an effective cancer treatment while maintaining the patient's quality of life,” said Dr. Inderbir Gill, founding executive director for USC Urology, part of Keck Medicine of USC. Gill is also Distinguished Professor & Chairman, Catherine & Joseph Aresty Department of Urology and Shirley & Donald Skinner Chair of Urological Cancer Surgery at Keck School of Medicine of USC.

Reza Zadno, CEO of PROCEPT BioRobotics, remarked, "Receiving IDE approval to explore Aquablation Therapy for men with localized prostate cancer marks a pivotal moment for PROCEPT. While our primary commitment is to establish ourselves as the standard of care for the treatment of BPH, we acknowledge the distinctive potential of our robotic system to address other urological indications." Zadno added, "Our aim is to bolster the clinical evidence through this study and collaborate with some of the nation's foremost cancer physicians.”

PROCEPT BioRobotics will post an updated investor presentation to its website, www.procept-biorobotics.com, on the “News & Events” page under the “Investors” tab.

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 therapy 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. 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 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 the possible initiation of clinical trials, potential regulatory approvals for additional indications, market opportunity and penetration, commercial momentum, overall business or the overall macroeconomic environment, which may impact customer spending or the Company’s financial performance. 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 filed with the SEC on February 28, 2023. 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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