PROCEPT Announces 5-Year WATER Study Data Comparing Aquablation to TURP

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– Symptom reduction and uroflow improvement proved durable and consistent compared to TURP

– Larger prostates (≥50 ml) demonstrated a larger safety and efficacy benefit for Aquablation over TURP

– 5-year Aquablation retreatment rate was 51% less compared to TURP

REDWOOD CITY, Calif., Feb. 14, 2022 (GLOBE NEWSWIRE) -- PROCEPT BioRobotics Corporation (Nasdaq: PRCT), a surgical robotics company focused on advancing patient care by developing transformative solutions in urology, today announced positive five-year results from its 181 patient randomized WATER study comparing Aquablation therapy to TURP, the historical standard of care for treating BPH.

WATER is the only prospective, randomized, double-blind, multicenter FDA pivotal study comparing the safety and efficacy of Aquablation to TURP. The study proved superior safety due to low irreversible complications and also superior symptom relief for prostates in the range of 50 milliliters or greater.

At five years, IPSS scores improved by 15.1 points in the Aquablation group and 13.2 points in TURP (p=.2764). However, for men with larger prostates greater than 50 milliliters, IPSS reduction was 3.5 points greater across all follow-up visits in the Aquablation group compared to the TURP group (p=.0123). Improvement in peak urinary flow rate was 125% and 89% compared to baseline for Aquablation and TURP, respectively. Retreatment rates, defined as needing BPH medication or surgical intervention, was approximately 1% per year for Aquablation, which was a 51% reduction compared to TURP.

“The urological community has been waiting to see if the early, pronounced benefits from Aquablation would remain over time. With the 5-year data from a randomized study now available, the Aquablation results are quite durable and look to have a very low rate of men needing an additional treatment. Given the broader range of prostate size and anatomy Aquablation can treat, this technology has the potential to change the paradigm of how BPH is treated,” said Dr. Alexis E. Te [1], Professor of Urology at the Weill Medical College at Cornell University.

“Based on our 5-year WATER data and real-world experience, we believe Aquablation therapy is poised to become the treatment of choice for BPH as it addresses the compromise between safety and efficacy. This study reinforces the durability of Aquablation therapy, and we are thrilled that men everywhere suffering from BPH now have a surgical treatment option with proven clinical outcomes, independent of the size and shape of the prostate, and a reduced risk of sexual side effects,” said Reza Zadno, President and Chief Executive Officer of PROCEPT BioRobotics.

To view the publication, visit: https://www.canjurol.com/html/free-articles/Cdn_JU29_I1_05_FREE_DrGilling.pdf

[1]Dr. Alexis E. Te was a study site principal investigator for the WATER study and consultant to PROCEPT BioRobotics.

About PROCEPT BioRobotics Corporation

PROCEPT BioRobotics is a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. PROCEPT 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 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 has developed a significant and growing body of clinical evidence, which includes nine clinical studies and over 100 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 statements regarding the potential utilities, values, benefits and advantages of Aquablation® therapy performed using PROCEPT’s 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 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 PROCEPT’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 PROCEPT’s filings with the Securities and Exchange Commission (the “SEC”), including PROCEPT’s quarterly report on Form 10-Q for the quarter ended September 30, 2021. PROCEPT 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’s 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. The most common side effects are mild and transient, and may include mild pain or difficulty when urinating, discomfort in the pelvis, blood in the urine, inability to empty the bladder or a frequent and/or urgent need to urinate, and bladder or urinary tract infection. Other risks include ejaculatory dysfunction and a low risk of injury to the urethra or rectum where the devices gain access to the body for treatment. For more information about potential side effects and risks associated with Aquablation therapy, speak with your urologist or surgeon. No claim is made that the AquaBeam Robotic System will cure any medical condition, or entirely eliminate the diseased entity. Repeated treatment or alternative therapies may sometimes be required.

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