PROCEPT BioRobotics Received U.S. FDA Approval to Initiate Pivotal Randomized Clinical Study for Prostate Cancer

October 7, 2024

A Prospective, Randomized, Multicenter Study Assessing the Safety and Efficacy of Aquablation Therapy in Men with Grade Group 1 to 3 Localized Prostate Cancer

Represents Potential Paradigm Shift in How Urologists Might Treat Localized Prostate Cancer

SAN JOSE, Calif., October 7, 2024 -- PROCEPT BioRobotics® Corporation (Nasdaq: PRCT) (the "Company"), a surgical robotics company focused on advancing patient care by developing transformative solutions in urology, today announced the U.S. Food and Drug Administration (FDA) has approved a pivotal Investigational Device Exemption (IDE) clinical trial comparing Aquablation therapy to radical prostatectomy. The Company also recently received Breakthrough Device Designation to investigate the use of Aquablation therapy for prostate cancer. Breakthrough Device Designation is awarded in exceptional cases, expediting the review of novel therapies that can improve the lives of people with life-threatening or irreversibly debilitating diseases or conditions.

The trial, known as WATER IV PCa, is a global multicenter, prospective, randomized clinical study assessing the safety and efficacy of Aquablation therapy compared to radical prostatectomy in men with Grade Group 1 to 3 localized prostate cancer. The study will enroll up to 280 patients at up to 50 centers and follow them for 10 years. There is a co-primary endpoint based on morbidity evaluated at the six-month follow-up. Longer-term follow-up focuses on both the reduction in treatment related harm and oncologic events.

"WATER IV PCa, a unique and thoughtful trial design focusing on harm reduction by using Aquablation as first line treatment in comparison to radical prostatectomy, could potentially change the way urologists treat localized prostate cancer for millions of men," said, Inderbir Gill, MD, founding executive director of USC Urology, part of Keck Medicine of USC and chairman, Catherine & Joseph Aresty Department of Urology, Keck School of Medicine of USC. "It is exciting to see that the FDA approved an IDE after a prompt and thorough review of the trial design, and we look forward to seeing the results of the forthcoming trial and are hopeful about the possibilities of this novel technology."

"A significant opportunity exists to improve safety and quality of life outcomes for men needing treatment for prostate cancer. We believe Aquablation therapy has the ability to become a first line treatment for localized prostate cancer. Initiating a randomized trial against radical prostatectomy is the first big step in pursuing a prostate cancer specific indication– which no other energy-based treatment has today," said Reza Zadno, Chief Executive Officer of PROCEPT BioRobotics.

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 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. 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 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 and statements regarding the potential utilities, values, benefits and advantages of Aquablation® therapy performed using PROCEPT BioRobotics' products, including the HYDROS™ 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 filed with the SEC on 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://www.procept-biorobotics.com/safety-information.

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

Media Contact:
Lauren Cohen
Senior Director, Integrated Marketing Communications
l.cohen@procept-biorobotics.com