



PROCEPT BioRobotics Completes Enrollment of Pivotal Clinical Trial for the Treatment of Benign Prostatic Hyperplasia

First study to directly compare the safety and effectiveness of Aquablation of the prostate with transurethral resection of the prostate for patients with lower urinary tract symptoms due to benign prostatic hyperplasia

REDWOOD SHORES, California, January 10, 2017 – PROCEPT BioRobotics, a Silicon Valley robotics company developing intelligent surgical solutions to treat prostate disease, announced today the completion of patient enrollment into the global Phase III WATER Study (**W**aterjet **A**blation **T**herapy for **E**ndoscopic **R**esection of prostate tissue).

The WATER Study is a double-blind, prospective, randomized clinical trial for male patients between the ages of 45 and 80 years old who have urinary symptoms due to benign prostatic hyperplasia (BPH). The Study, conducted under U.S. investigational device exemption (IDE), evaluates the safety and effectiveness of the AQUABEAM® System as compared to transurethral resection of the prostate (TURP). The primary end points of safety and effectiveness will be measured at three and six months respectively, and patients will be followed to three years to collect long-term clinical data.

The AQUABEAM System combines real-time prostate imaging and surgical robotics to deliver Aquablation, a waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue for the treatment of lower urinary tract symptoms caused by BPH. Built-in simultaneous cystoscopic and intra-procedural ultrasound image guidance empowers the surgeon with improved decision making by enabling the surgeon to draw a treatment contour that conforms to the shape of the prostate adenoma while sparing the anatomical landmarks responsible for continence and ejaculatory function. The robotically controlled waterjet then precisely and efficiently resects the adenomatous tissue according to the prescribed treatment plan.

“The robust design of the WATER Study will provide us with comprehensive data related to the safety and effectiveness of Aquablation and a solid comparison to TURP, the most common procedure performed world-wide for the treatment of lower urinary tract symptoms due to BPH,” said co-principal investigator Claus Roehrborn, MD, Chair of the Department of Urology at UT Southwestern in Dallas, Texas. “Thanks to the focus and commitment of the high-performing centers across three continents, we were able to complete enrollment of this ambitious study without delay.”

“By combining image guidance and robotics, the AQUABEAM System has the potential to standardize BPH surgery through improved decision making and procedural predictability,” said co-principal investigator Peter Gilling, MD, Professor of Surgery at the University of Auckland, Tauranga Hospital, Tauranga, Bay of Plenty, New Zealand. “We were the first center to utilize this technology four years ago, and it has been exciting to witness the short learning curve at 16 other centers resulting in reproducible outcomes with this technology.”

The WATER Study successfully enrolled 184 patients at 17 sites across four countries. “It was a tremendous accomplishment to complete this rigorous clinical trial in one year, and I want to acknowledge each of the sites and their investment in clinical research,” said Nikolai Aljuri, Ph.D., co-founder and Chief Executive Officer of PROCEPT BioRobotics. “The completion of the WATER Study is an

important step in achieving our goal of bettering the lives of men suffering from BPH, by developing a minimally invasive solution that offers both a sustained and significant improvement to quality of life and a reduced risk of sexual side effects.”

About Benign Prostatic Hyperplasia (BPH)

BPH is a common prostate problem affecting about 50% of men between the ages of 51 and 60 and up to 90% of men older than 80. As many as 20 million men in the United States have lower urinary tract symptoms suggestive of BPH. While effective for some, BPH medications are typically only used to treat mild to moderate symptoms and are associated with bothersome side effects including retrograde ejaculation and other sexual side effects, as well as nausea and dizziness. The most common surgical procedures to treat BPH today are transurethral resection of the prostate (TURP) and laser therapy, both of which utilize heat to remove the enlarged prostate tissue. These surgical methods are successful at removing the enlarged tissue, but have been shown to have significant complications.

About PROCEPT BioRobotics

Based in Silicon Valley, PROCEPT BioRobotics is enabling better patient care by developing robotic surgical solutions to treat prostate disease. With an initial focus on benign prostatic hyperplasia (BPH), the company has developed the AQUABEAM System, which leverages the company’s core Aquablation technology. Aquablation is a precise and controlled waterjet ablation therapy that enables heat-free and immediate removal of prostate tissue. The AQUABEAM System utilizes intra-procedural ultrasound imaging to enable real-time surgical planning and mapping of the prostate, followed by robotically controlled Aquablation of the defined resection area. The combination of surgical mapping and controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size and shape. The AQUABEAM System is available for investigational use only in the United States and not currently available for sale in the United States. The AQUABEAM System has CE Mark clearance and will be available in select global markets in 2017.

For additional information, please visit www.procept-biorobotics.com.

For more information, please contact:

PROCEPT BioRobotics

Matt Salkeld Vice President, Sales & Marketing

+1-650-232-5787

m.salkeld@procept-biorobotics.com

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