PROCEPT BioRobotics Announces First Patients Treated in WATER II Pivotal Clinical Trial

Study Will Evaluate the Safety and Efficacy of Aquablation in Large Prostates for Patients with Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia

REDWOOD SHORES, Calif. – September 27, 2017 – PROCEPT BioRobotics, a Silicon Valley robotics company developing intelligent surgical solutions to treat prostate disease, has announced that the first patients have been treated in the WATER II Study (**W**aterjet **A**blation **T**herapy for **E**ndoscopic **R**esection of prostate tissue). The WATER II study is a U.S. investigational device exemption (IDE) clinical trial evaluating the safety and efficacy of Aquablation, delivered with the company's AQUABEAM® System, in large prostates 80 to 150 milliliters (mL) for the treatment of benign prostatic hyperplasia (BPH).

The co-principal investigators for the WATER II study are Claus Roehrborn, MD, Chair of the Department of Urology at University of Texas Southwestern; James Lingeman, MD, at Indiana University School of Medicine; and Mihir Desai, MD, at Keck Hospital, University of Southern California. The study will enroll 100 patients at up to 20 sites in the U.S. and Canada, with patient follow-up out to 12 months. Mohamed Bidair, MD, initiated the trial at Sharp Grossmont Hospital in San Diego, enrolling nine patients over two days, including seven patients with an estimated prostatic volume close to 150 mL.

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. 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 WATER II Study is a follow-up study to the successful WATER Study, which showed a superior safety profile for Aquablation with very strong efficacy outcomes comparable to transurethral resection of the prostate (TURP) for the treatment of BPH in prostates size 30 to 80 mL. Fourteen of the 17 sites had no prior Aquablation experience and a median of five patients treated with Aquablation per participating surgeon. Furthermore, a pre-specified subgroup of men from the WATER Study with a prostate size between 50 and 80 mL had statistically superior improvements in IPSS after Aquablation compared to TURP.

"The WATER Study was able to demonstrate that Aquablation achieves superior safety and efficacy results in men with larger glands. The WATER II study has been designed to further validate those results in prostates up to 150 milliliters in volume where current surgical options are more limited," said Dr. Roehrborn.

Based on the 2010 American Urological Association Guidelines, open prostatectomy typically is performed on patients with prostate volumes greater than 80 to 100 mL. However, there is significant risk of blood loss, transfusion and a longer hospital stay associated with open prostatectomy. Emerging evidence suggests a possible role of transurethral enucleation as an option for men with large prostates greater than 100 mL, although the procedural technique is more complex and not broadly utilized.

“Prostates greater than 80 mL provide an increased level of surgical complexity. The AQUABEAM System provides intra-operative image guidance that allows the surgeon to develop an optimal tissue removal plan followed by the precision of a robotically executed waterjet,” said Dr. Desai. “Aquablation has the potential to standardize treatment and deliver predictable and reproducible results regardless of the size of the prostate.”

“Aquablation is a promising technology for patients with BPH, offering a minimally invasive alternative to open prostatectomy,” said Dr. Bidair. “We are encouraged by the results of the WATER Study and look forward to exploring the potential benefits of this treatment option for those with larger prostates, a very common condition in older men that heretofore required open surgical intervention with a prolonged postoperative recovery course.”

About Benign Prostatic Hyperplasia (BPH)
BPH is a common prostate problem affecting about 50 percent of men between the ages of 51 and 60 and up to 90 percent 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 is available for investigational use only in the U.S. and not currently available for sale in the U.S. or Canada. The AQUABEAM System has received CE Mark certification and is available in select global markets.
www.PROCEPT-BioRobotics.com.

MEDIA CONTACTS:
Diana Soltesz
Nobles Global Communications
+1-818-618-5634
diana@noblesgc.com

###