



PROCEPT BioRobotics' Aquablation Shows Superior Results vs. TURP in WATER Blinded Randomized Trial for BPH

Aquablation Demonstrates TURP-like Efficacy with Reduced Rate of Sexual Side Effects

REDWOOD SHORES, Calif. – May 14, 2017 – PROCEPT BioRobotics, a Silicon Valley robotics company developing intelligent surgical solutions to treat prostate disease, has announced the early safety and efficacy endpoints from the global Phase III WATER (**W**aterjet **A**blation **T**herapy for **E**ndoscopic **R**esection of prostate tissue) Study showing a superior safety profile for Aquablation with very strong efficacy outcomes comparable to transurethral resection of the prostate (TURP) for the treatment of benign prostatic hyperplasia (BPH). Presented today at the American Urological Association (AUA) Annual Meeting in Boston, the data demonstrated that use of Aquablation resulted in a large improvement in patient symptoms, a substantial increase in urinary flow rates and a decreased risk of sexual side effects compared to TURP.

Aquablation, delivered by PROCEPT BioRobotics' AQUABEAM® System, uses a robotically controlled waterjet to remove prostate tissue without the application of heat. The double blind, prospective, randomized WATER Study compared Aquablation to TURP in 181 male patients, age 45 to 80 years with urinary symptoms due to BPH, at 17 sites across four countries. As reported by Co-principal Investigator, Claus Roehrborn, MD, Chair of the Department of Urology at UT Southwestern in Dallas, Texas, the study met its primary endpoints, indicating that surgeons were able to deliver high-quality TURP-like outcomes using Aquablation.

“With the results in the TURP cohort providing a very strong control group, the WATER Study was able to demonstrate that Aquablation achieves comparable overall outcomes for the subjective and objective efficacy measures with even better results in larger glands,” said Dr. Roehrborn.

A summary of the reported findings of the WATER Study comparing Aquablation to TURP includes:

- Significantly improved BPH symptoms in both treatment groups as measured by the International Prostate Symptom Score (IPSS) at six months with 100% of Aquablation patients improving from baseline
- Superiority in IPSS storage symptom sub-scores ($p < 0.05$)
- Superiority in IPSS improvement with Aquablation in men with prostate volume greater than 50 ml as compared to TURP ($p < 0.01$)
- Superiority in peak urinary flow rates (Q_{max}) at six months
- A significantly lower rate (4 to 1 ratio, $p < 0.001$) of sexual side effects in Aquablation compared to TURP at three months
- Superiority in ejaculatory function (MSHQ-EJD) and incontinence scores (ISI) at three months

“These results indicate that the learning curve with Aquablation is very short in relation to TURP, as a majority of the physicians achieved TURP-like results without any prior experience with Aquablation,” said Co-principal Investigator Peter Gilling, MD, Professor of Surgery at the University of Auckland, Bay of Plenty Clinical School Tauranga. “The combination of image guidance and robotics allows the surgeon to identify critical anatomical landmarks and develop an optimal tissue removal plan that seems to provide predictable and reproducible results.”

BPH is a highly prevalent condition affecting approximately 50 percent of men age 60 or older and 90 percent of men age 85 or older.¹ About half of men diagnosed with BPH experience moderate-to-severe lower urinary tract symptoms (LUTS). Today, patients must decide to treat their BPH with surgical treatments such as TURP, which offer sustained symptom relief but a high risk of complications, or minimally invasive techniques that have a low risk of complications but are less effective for symptom relief. Investigational technologies like Aquablation offer the potential for symptomatic improvement similar to TURP with a superior safety profile.

“This is a significant milestone for Aquablation and PROCEPT BioRobotics in our goal of bettering the lives of men suffering from BPH,” said Nikolai Aljuri, Ph.D, co-founder and chief executive officer at PROCEPT BioRobotics. “The early results of this landmark study challenge the gold standard and suggest that Aquablation could become the treatment of choice offering men a sustained and significant improvement in quality of life with a superior safety profile and reduced risk of sexual side effects.”

About the AQUABEAM System and Aquablation

The AQUABEAM System is the only surgical technology for Benign Prostatic Hyperplasia (BPH) that combines intra-procedural ultrasound 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. By combining traditional cystoscopic visualization with ultrasound imaging, the AQUABEAM System provides a real-time multi-dimensional view of the prostate, empowering the surgeon with improved decision making during the procedure. Prior to resection, the surgeon uses the AQUABEAM monitor to define the area of resection while sparing the anatomical landmarks responsible for continence and ejaculatory function. The robotically controlled waterjet then resects the tissue according to the prescribed treatment plan. 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 and not currently available for sale in the United States. The AQUABEAM has CE Mark approval, TGA approval and MedSafe registration and is now available in select global markets.

About PROCEPT BioRobotics

Based in Silicon Valley, PROCEPT BioRobotics is bettering the lives of men 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 Aquablation therapy, the company’s core technology platform. Aquablation is a precise and controlled waterjet ablation therapy that enables heat-free and immediate removal of prostate tissue.

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

¹ <http://emedicine.medscape.com/article/437359-overview#a2>

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