PROCEPT BioRobotics Presents Phase II Data on Treatment of Benign Prostatic Hyperplasia with Aquablation using the AQUABEAM®

Data demonstrate the performance and the preliminary safety and effectiveness of a novel image-guided robotic surgical system that uses high velocity saline to efficiently resect prostate tissue

REDWOOD SHORES, California, May 15, 2015 – PROCEPT BioRobotics, a clinical-stage medical device company, announced today the results of a Phase II study investigating the safety and feasibility of Aquablation, a minimally invasive water ablation therapy, for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). The AQUABEAM® is a first of its kind image-guided system delivering a treatment utilizing water and robotics for the targeted removal of prostate tissue. The data were presented at the American Urological Association Annual 2015 meeting in New Orleans, La.

The Aquablation procedure had a 100 percent technical success rate in 21 patients and reduced symptoms demonstrated by a 15.9 point decrease in the mean International Prostate Symptom Score (IPSS) at 6 months. Improvement in urine flow was also observed with a 10.1mL/sec increase in the peak urinary flow rate (Qmax; from 8.6 to 18.7mL/sec). The mean procedure and resection times were 38 minutes and five minutes, respectively. Post-operative dysuria (painful urination) was minimal and adverse events were typically mild and transient. There was no occurrence of urinary incontinence or loss of ejaculatory or erectile function in the study.

“Aquablation is a minimally invasive technique that results in efficient and precise resection of prostate tissue and may lessen the risks and discomfort associated with prostate surgical procedures,” said Peter Gilling, M.D., Associate Professor of Surgery at Grace Prostate Cancer Center, Tauranga, Bay of Plenty, New Zealand and lead author of the study. “The technology developed by PROCEPT BioRobotics has the potential to standardize benign prostatic hyperplasia surgery, reduce the level of complexity required to deliver safe and effective therapy and ultimately improve the quality of life for men suffering from benign prostatic hyperplasia.”

BPH is a non-cancerous enlargement of the prostate gland which can result in irritation or blockage of the urethra, the tube that carries urine out of the body from the bladder. BPH may lead to difficulty urinating, incontinence, bladder infections and the formation of stones or kidney damage. One out of every two men over the age of 50 develop symptoms of BPH, and one out of ten will need surgical intervention to remove part of the prostate.¹ Standard surgical procedures for BPH utilize heat (high thermal energy
technologies) to remove or reduce the size of the prostate to improve symptoms and urine flow.

“Interventional therapy is an option to alleviate symptoms for men who fail medical management of benign prostatic hyperplasia, but current options are a trade-off between improvement of patient symptoms and a risk of complications. There is a need for a minimally invasive solution that offers a sustainable and significant improvement to quality of life and a reduced risk of adverse effects, including sexual side effects,” said Nikolai Aljuri, Ph.D., founder and chief executive officer of PROCEPT BioRobotics. “Our results represent a step in the right direction as they suggest the potential for Aquablation to revolutionize the prostate treatment paradigm. We look forward to the initiation of the W.A.T.E.R study, our global Phase III clinical study evaluating the safety and effectiveness of AQUABEAM as compared to the current standard of care, transurethral resection of the prostate, or TURP.”

The W.A.T.E.R study (Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue) is a prospective randomized blinded controlled clinical trial that will begin later this year. The AQUABEAM is under clinical investigation and not currently available for sale in the United States.

About Aquablation Pilot Study for the Treatment of Benign Prostatic Hyperplasia
The aim of this prospective multicenter, clinical trial was to establish the safety and performance of Aquablation for the treatment of benign prostatic hyperplasia. The study enrolled 21 patients at two sites in Australia and one site in New Zealand. The study evaluated the pre-, intra- and post-operative complication rate, quality of life symptoms, urinary flow rate, and urodynamic obstruction as confirmed by urodynamics (evaluating the storing and releasing of urine from the body). Follow-up is planned through three years.

About Benign Prostatic Hyperplasia
Benign prostatic hyperplasia (BPH), otherwise known as enlarged prostate, is a common prostate problem affecting up to one out of two men between the ages of 51 and 60 and nine out of 10 men over the age of 80 suffer from the condition.² Although BPH rarely causes symptoms before age 40, the occurrence and symptoms increase with age. In 2010, nearly 14 million men in the United States and 30 million men worldwide had lower urinary tract symptoms suggestive of BPH.³

About PROCEPT BioRobotics
PROCEPT BioRobotics is a medical device company that develops a novel minimally invasive technology to surgically treat prostate disease. The first product developed is the AQUABEAM, an intelligent image-guided system delivering Aquablation, a personalized waterjet tissue resection modality. Under real-time image-based ultrasonic guidance, AQUABEAM enables surgical planning and mapping, and allows for a controlled resection of the prostate with a high-velocity saline stream. The combination of surgical mapping and controlled resection of the prostate is designed to offer predictable and reproducible outcomes which will enable quicker adoption and scaling
of the technology. The company is privately held and headquartered in Redwood Shores, California.

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

References


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