Profound Medical seeking CE Mark for TULSA-PRO this year

By
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Profound Medical, which is going public next week, figures that data from a 30-patient safety and feasibility study of its transurethral ultrasound ablation (TULSA) technology for minimally invasive treatment of prostrate cancer will be sufficient to file for CE Mark approval in Europe before the end of 2015.

Steven Plymale

“We hope to launch TULSA-PRO in Germany during 2016 with a direct sales force in order to develop close relationships with early adopters and control our reimbursement strategy,” CEO, Steven Plymale, says in an interview with BioTuesdays.com.

“Our strategy is to seek high volume sites treating prostate cancer as a way to boost revenue,” he suggests. “We’re not selling high-cost capital equipment, but rather the disposables used in each treatment.”

Mr. Plymale says Profound plans to launch TULSA-PRO with eight-to-10 sales reps in Europe during the first two years and then add to its sales team as the business grows. “We expect to be cash flow positive by the end of 2017.”

The company also plans to seek a Canadian medical device license in early 2016 and launch TULSA-PRO with distribution partner Knight Therapeutics.

In the U.S., he says Profound will be seeking IDE approval this year to begin a pivotal study with approximately 110 patients, leading to an FDA *de novo* filing and possible launch before the end of 2017. The pivotal study is expected to be conducted at five-to-six sites in the U.S., three in Europe and two in Canada.

TULSA-PRO offers the potential to treat patients with localized prostate cancer, using real-time image guidance in a minimally invasive 40-minute procedure. Patients could be treated as an outpatient, depending on the time of the procedure, with the same or even better quality of life outcomes than surgery or radiation. “That’s our value proposition,” he contends.

Mr. Plymale explains that the treatment uses an innovative, transurethral ultrasound applicator (UA) to ablate an entire prostate gland from within the gland, in just one treatment session. Using real-time MRI image guidance, TULSA-PRO delivers a highly accurate and precise treatment, destroying the prostate tissue, including the cancerous tissue, while sparing surrounding tissue, he adds.

The procedure takes place within an MRI scanner, which provides real-time image-guidance and temperature feedback of the prostate being ablated. “During treatment, the UA is inserted into the prostate and rotated 360 degrees, emitting ultrasound energy precisely toward the patient-specific prostate boundary, destroying the prostate tissue but sparing surrounding tissue,” he suggests.

In addition, he says our software-controlled algorithm takes real-time MRI temperature data to adjust the energy intensity and rate of rotation of the UA, resulting in precise conformal targeting of the prostate tissue.

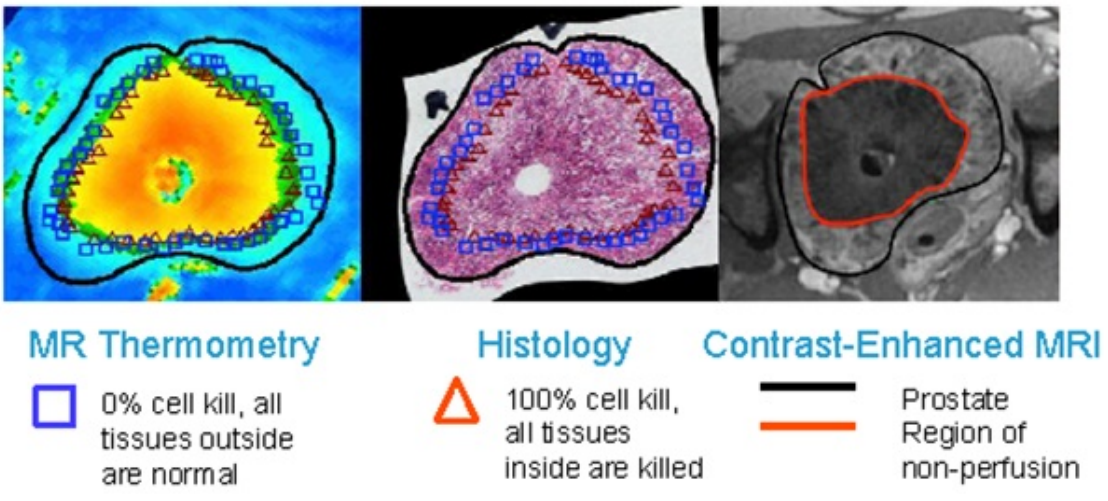
According to Mr. Plymale, one-in-seven men will be diagnosed with prostate cancer in their lifetime. There are some 500,000 new cases diagnosed each year around the world, with 850,000 annual procedures across the entire spectrum of the disease.

Prostate cancer represents a $40-billion market opportunity, with surgery and radiation making up the lion’s share of the market.

However, surgery and radiation bring undesirable complications, including erectile dysfunction (ED), incontinence and GI tract problems. “ED, following surgery, falls in a range of 50% to 70% and even higher,” Mr. Plymale points out.

He contends that Profound’s technology results in fewer significant complications. Twelve-month follow-up of 30 patients demonstrated virtually no incidence of incontinence and GI toxicity, he claims. “We’re now seeing rates of erectile dysfunction at around 16% with TULSA-PRO, well below rates following surgery.”

In addition, he points out that testing in prostates showed excellent agreement between MRI temperature measurements, histology and contrast-enhanced MRI with TULSA-PRO.

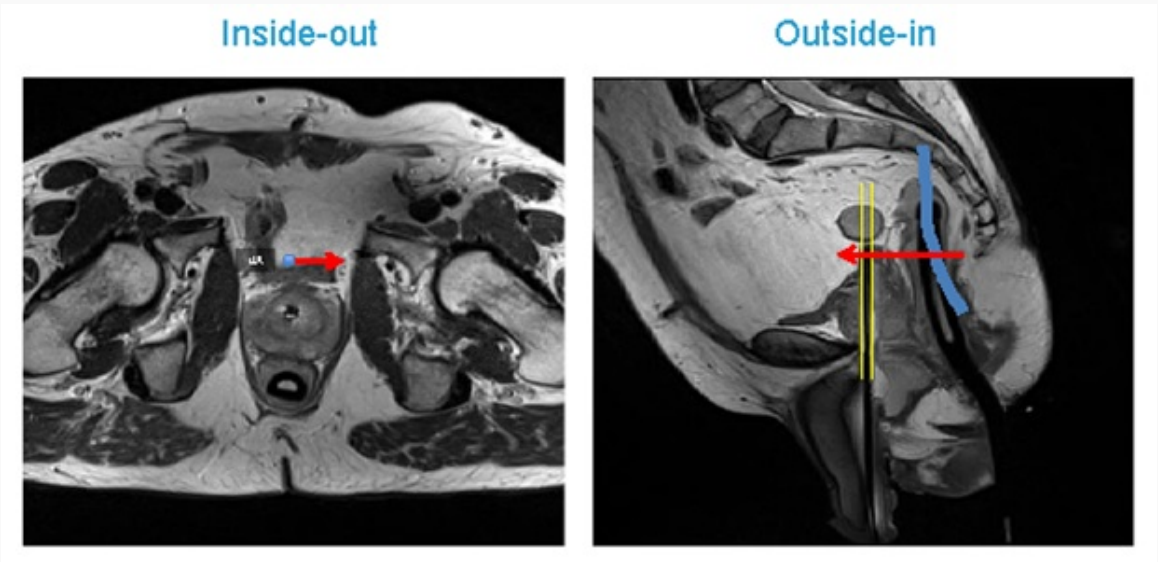


Proven Accuracy: Testing in Prostates Showed Excellent Agreement Between MRI Temperature Measurements, Histology and Contrast-enhanced MRI

TULSA-PRO also stacks up well against high intensity-focused ultrasound (HIFU), a competing solution that uses ultrasound heat to destroy the area of the prostate gland affected with cancer.

HIFU employs a rectal probe that gives out a focal beam of high-intensity ultrasound through the rectal wall to the prostate, creating rice-sized lesion. It needs to lays down hundreds of rice-sized lesions, one on top of the other, to cover about 40 cubic centimeters of prostate tissue and takes about three hours.

In contrast, Mr. Plymale says the transurethral TULSA-PRO probe does a single sweep in 40 minutes to ablate the entire prostate gland, covering an area as large as 100 cubic centimeters. “Our preclinical data observed that 83% of urethral tissue was preserved after treatment, along with no damage to urethral sphincters, bladder neck or rectal wall, resulting in good quality of life outcomes.”



Reduced Tissue Damage: Preclinical Study Observed 83% of Urethral Tissue Was Preserved After Treatment

Before the end of the month, Profound expects to receive gross proceeds of $29.7-million from a private placement, debt financing and reverse merger as it obtains a public listing (TSX-V:PRN).

“Our goal is to have our device rolling into each MR scanner in Europe as doctors look at image guided therapy as a way to treat patients with minimally invasive tools,” Mr. Plymale says. “Our colleagues in the MR industry see this as the operating room of the future for applications beyond prostate cancer.”

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