Initial Data from Profound Medical's TACT Pivotal Clinical Trial Presented at AUA 2018

TORONTO, May 21, 2018 -- Profound Medical Corp. (TSX-V:PRN) (OTCQX:PRFMF) ("Profound" or the "Company"), the only company to provide a therapeutics platform that provides the precision of real-time Magnetic Resonance ("MR") imaging combined with the safety and ablation power of directional and focused ultrasound technology for the incision-free ablation of diseased tissue, announced that initial data from the TACT (TULSA-PRO® Ablation Clinical Trial) pivotal study are being presented today during a plenary session at the American Urological Association ("AUA") Annual Meeting in San Francisco, CA.

TACT, a prospective, open-label, single-arm pivotal clinical study, enrolled 115 patients with biopsy-proven, organ-confined prostate cancer across 13 research sites in the United States, Canada and Europe. The pre-treatment median age of the patients enrolled in TACT was 64 years, median PSA was 6.5 ng/ml, and 61% and 39% of patients had Gleason Score 7 and 6 disease, respectively.

The primary efficacy endpoint of TACT is the proportion of patients achieving a post-treatment prostate-specific antigen ("PSA") reduction ≥ 75% of their pre-treatment baseline value. The Company's pre-established performance goal for the success proportion is 50% of patients.

In his presentation at AUA 2018, Laurence Klotz, M.D., a world-renowned expert in prostate cancer and investigator in the TACT trial, reported that the median PSA reduction to-date is 95% (nadir 0.36 ng/ml), and 95% (109 out of 115) patients have met the PSA endpoint.

The primary safety endpoint of TACT is the frequency and severity of adverse events. The rate and nature of attributable serious adverse events were similar to those reported in the Phase I Safety & Feasibility Study (Chin et al, Eur Urol 2016) of TULSA-PRO®, occurring in 7% of patients, including 2.6% urinary retention, 2.6% infection, 0.9% urinoma, 0.9% ileus (related to urinary catheter) and 0.9% deep vein thrombosis, all resolved. There was no rectal injury or fistula, no unresolved urinary incontinence > Grade 1, and no Grade ≥ 4 adverse events.

Additional secondary endpoints of TACT are focused on quality-of-life side effects commonly associated with current prostate cancer therapies, such as erectile dysfunction and urinary incontinence. As the standard evaluation period for these side effects is 12 months post-treatment, the sample size of evaluable patients is not yet large enough to assess.

"Approximately two-thirds of the prostate cancer patients enrolled in the TACT pivotal trial had intermediate-risk disease, a group for whom the current gap between active surveillance and invasive treatments such as radical prostatectomy and radiation is often too wide," said Dr. Klotz. "TULSA-PRO® is a minimally-invasive, image-guided procedure designed to precisely ablate the prostate with the goal of reducing the risk of side-effects commonly associated with other treatments. This data, while preliminary, is encouraging and I am very much looking forward to seeing the complete 12-month results."

"We are impressed to see the significant reduction in the PSA of the patients treated in the TACT pivotal study," commented Arun Menawat, Profound's CEO. "We continue to expect that, once the full results are available, data from TACT will help pave the path for the successful commercialization of TULSA-PRO® in the United States and help further drive clinical adoption of the technology in Europe."

About Profound Medical Corp.

The Profound Medical Corp. team is committed to creating the powerful combination of real-time MR-guidance as the imaging platform and ultrasound as the energy source for delivering non-invasive ablative tools to clinicians. These key technology pillars, linked with intelligent software and robotics, have the potential to fulfill unmet needs of patients and clinicians in many anatomies and disease states, including prostate cancer, uterine fibroids, and bone metastases. Our mission is to profoundly change the standard of care by creating a tomorrow where clinicians can confidently ablate tissue with precision; a tomorrow where patients have access to safe and effective treatment options, so they can quickly return to their daily lives.

Profound is commercializing a novel technology, TULSA-PRO®, which combines real-time Magnetic Resonance Imaging with transurethral, robotically-driven therapeutic ultrasound and closed-loop thermal feedback control that is designed to provide precise ablation of the prostate while simultaneously protecting critical surrounding anatomy from potential side effects. TULSA-PRO® is CE marked and Profound is currently conducting a pilot commercial launch of the technology in key European and other CE mark jurisdictions. The Company is also sponsoring a multicenter, prospective FDA-registered clinical trial, TACT, which, if successful, is expected to support its application to the FDA for clearance to market TULSA-PRO® in the United States.

Profound Medical is also commercializing Sonalleve®, an innovative therapeutic platform that combines real-time MR imaging and thermometry with thermal ultrasound to enable precise and incision-free ablation of diseased tissue. Sonalleve® is CE marked for the treatment of uterine fibroids and palliative pain treatment of bone metastases. The technology was recently approved by the Chinese Food and Drug Administration for the non-invasive treatment of uterine fibroids. The Company is also in the early stages of exploring additional potential treatment markets for Sonalleve®, such as non-invasive ablation of abdominal cancers and hyperthermia for cancer therapy, where the technology has been shown to have clinical application.

Forward-Looking Statements

This release includes forward-looking statements regarding Profound and its business which may include, but is not limited to, the expectations regarding the efficacy of Profound's technology in the treatment of prostate cancer, uterine fibroids and palliative pain treatment. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "is expected", "expects", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Such statements are based on the current expectations of the management of Profound. The forward-looking events and circumstances discussed in this release, may not occur by certain specified dates or at all and could differ materially as a result of known and unknown risk factors and uncertainties affecting the company, including risks regarding the pharmaceutical industry, economic factors, the equity markets generally and risks associated with growth and competition. Although Profound has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Profound undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, other than as required by law.

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