Press Release

Theralase Anti-Cancer Technology to be Presented at International Conference

Toronto, Ontario – October 25, 2016, Theralase Technologies Inc. ("Theralase®" or the "Company") (TLT:TSXV) (TLTFF:OTC), a leading biotech company focused on the commercialization of medical devices to eliminate pain and the development of Photo Dynamic Compounds ("PDCs") to destroy cancer, announced today that Dr. Lothar Lilge, Professor and Grad Student Coordinator, Medical Biophysics, University of Toronto, will be presenting Theralase’s anti-cancer technology at the Photodynamic Therapy and Photodiagnosis ("PDT-PDD") Conference taking place from October 24 to 28, 2016, in Nancy, France.

Dr. Lilge will deliver an oral and poster presentation on “TLD-1433-Mediated Photo Dynamic Therapy as a Novel Intravesical Treatment for Bladder Cancer: in vitro, in vivo, and Good Laboratory Practice ("GLP") Toxicology Validation”.

Urinary bladder cancer, which accounts for 3.3% of all cancers, is a socially significant healthcare problem that has become a major cause of morbidity, mortality, and health-related costs. Although first line treatments are initially effective at treating the tumour, the recurrence rate ranges from 60% to 70%. Photo Dynamic Therapy ("PDT") is a medical therapy where a photosensitizer ("PS") produces cytotoxic radical oxygen species upon light activation at a particular wavelength, causing cell death through apoptosis. PDT was initially approved by Health Canada for bladder cancer in 1993; however, the treatment has drawn criticism due to morbidity affecting the muscle layers and bladder function. Here we present a new approach to PDT treatment of bladder cancer using instillation of a novel water soluble ruthenium-based PS, known as TLD-1433 and the TLC-3200 (Theralase Inc., Toronto, Canada) laser and dosimetry system that was designed to emit and detect 525 nm laser light in the bladder.

Confocal microscope cellular uptake studies of TLD-1433 demonstrate that TLD-1433 is primarily localized in the cellular cytoplasm. Inductively Coupled Plasma - Mass Spectrometry ("ICP-MS") studies of tissue uptake after systemic injection in mice showed clearance within 24 hours from most tissue, while one hour TLD-1433 intravesical instillation into the rat bladder demonstrated minimal seepage into systemic circulation. Tumour versus normal urothelium uptake of TLD-1433 was measured in the orthotopic rat bladder model and preferential tumour uptake was observed (186x preferential uptake in bladder tumour versus normal urothelium).

Confirmatory preclinical studies utilizing “TLD-1433 only” or “Laser light only” treatments demonstrated no discernible effects on tumor growth rate, normal urothelium or bladder musculature. After 90 J/cm² 525 nm PDT treatment with TLD-1433, full depth tumor necrosis was observed at both 0.6 and 6.0 mg/mL instillation concentrations in the majority of tumours. Muscle invasive tumors were also destroyed by the PDT treatment to a depth of over 1 mm, while normal bladder muscle tissue was unaffected after PDT treatment. The urothelium showed local inflammation near the tumour that was beginning to resolve 48 hours post PDT, demonstrating the localized PDT effect to bladder cancer tumours only.

To establish the clinical safety of TLD-1433, GLP toxicology, pharmacodynamics and pharmacokinetics studies were performed in rat and dog models. The No Observed Adverse Effect Level ("NOAEL") dose in the systemic rat model was determined to be ≥ 6 mg/kg. No effects on body weight, food consumption, clinical pathology, ophthalmology, organ weight or macroscopic/microscopic observations were noted.
The NOAEL dose in the dog bladder intravesical instillation study was determined to be ≥3.5 mg/cm², which is much higher (~100 mg/kg) than the NOAEL dose for systemic injection, supporting Theralase’s approach for a photosensitizer intravesical instillation. There were no adverse effects in clinical observations, body weights, food consumption, organ weight, ocular degradation, cardiology or clinical pathology parameters attributable to administration of TLD-1433. There was no evidence of any systemic toxicity associated with the TLD-1433 test item in organs examined microscopically.

Representative images of control (A) and PDT treated tumours (B) (525 nm light at 90 J/cm²). The control tumour shows unabated growth, reaching a thickness of 2 to 3 mm of highly packed proliferating cells. The tumour treated with 6 mg/mL TLD-1433 mediated PDT shows full depth necrosis of the whole > 1 mm thick tumour.

As a result of a Clinical Trial Application (“CTA”) approval and a recent Investigational Testing Authorization (“ITA”) approval from Health Canada the Company is commencing a Phase Ib clinical study for Non-Muscle Invasive Bladder Cancer (“NMIBC”) entitled “A Phase Ib Trial of Intravesical Photodynamic Therapy in Patients with Non-Muscle Invasive Bladder Cancer at High Risk of Progression Who Are Refractory to Therapy with Bacillus Calmette-Guerin and Who Are Medically Unfit for or Refuse a Cystectomy”.

Dr. Lilge stated that, “The PDT-PDD Symposium in Nancy, France is the forum this year to showcase Theralase’s anti-cancer technology to the international PDT community and to commence building international relationships, with both the scientific and medical communities. This should allow Theralase to engage other urology sites for a subsequent Phase II clinical study, meant to validate the TLD-1433 for efficacy and the ultimate goal of proliferation of this technology globally. The photosensitizer, its administration and the light dose optimization / monitoring are all unique aspects for Theralase’s PDT technology.”

About Theralase Technologies Inc.
Theralase Technologies Inc. ("Theralase®" or the “Company”) (TSXV: TLT) (TLTFF: OTC) in its Therapeutic Laser Technology ("TLT") Division designs, manufactures, markets and distributes patented super-pulsed laser technology indicated for: elimination of pain, reduction of inflammation and dramatic acceleration of tissue healing for numerous nerve, muscle and joint conditions. Theralase’s Photo Dynamic Therapy ("PDT") Division researches and develops specially designed molecules called Photo
Dynamic Compounds ("PDCs"), which are able to localize to cancer cells and then when laser light activated, effectively destroy them.

Additional information is available at www.theralase.com and www.sedar.com.

This press release contains forward-looking statements, which reflect the Company’s current expectations regarding future events. The forward-looking statements involve risks and uncertainties. Actual results could differ materially from those projected herein. The Company disclaims any obligation to update these forward-looking statements.

Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchanges) accepts responsibility for the adequacy or accuracy of this release.

For More Information:
Roger Dumoulin-White
President & CEO
1.866.THE.LASE (843-5273) ext. 225
416.699.LASE (5273) ext. 225
rwhite@theralase.com
www.theralase.com