

Theralase Commences Phase II NMIBC Clinical Study

Toronto, Ontario – April 25, 2019, Theralase® Technologies Inc. (“**Theralase**” or the “**Company**”) (**TLT:TSXV**) (**TLTFF:OTCQB**), a clinical stage pharmaceutical company dedicated to the research and development of light activated Photo Dynamic Compounds (“**PDC**”) and their associated drug formulations intended to safely and effectively destroy various cancers, announced today that the University Health Network Research Ethics Board (“**UHN-REB**”) has approved the commencement of a Phase II clinical study to evaluate Theralase’s Anti-Cancer Treatment (“**ACT**”) titled, “Patients with Non-Muscle Invasive Bladder Cancer (“**NMIBC**”), who present with Carcinoma In-Situ (“**CIS**”), who are considered Bacillus Calmette Guérin (“**BCG**”) - Unresponsive or are intolerant to BCG Therapy (“**ACT-NMIBC**”)”.

The ACT-NMIBC study has been designed in compliance with FDA industry guidelines issued February, 2018 for BCG-unresponsive NMIBC. The study will utilize the Therapeutic Dose (0.70 mg/cm) of TLD-1433 and will focus on the treatment of approximately 100 to 125 BCG-unresponsive NMIBC patients, with CIS, in approximately 20 clinical study sites in Canada, the US and internationally, with a primary endpoint of efficacy and a secondary endpoint of safety.

Study sites will be launched first in Canada, followed by the US, subject to Food and Drug Administration approval, and then internationally, subject to international regulatory approval.

The primary endpoint of the Study:

Efficacy – Evaluated by Complete Response (“**CR**”) in patients with CIS with or without resected papillary disease at 90 days post-treatment with a duration of CR evaluated at 360 days post-treatment.

Patient CR is defined as:

1. Negative cystoscopy and negative (including atypical) urine cytology
2. Positive cystoscopy with biopsy-proven benign or low-grade NMIBC or
3. Negative cystoscopy with malignant urine cytology, if cancer is found in the upper tract or prostatic urethra and random bladder biopsies are negative

The secondary endpoint of the Study is:

Safety – Evaluated by the incidence and severity of Adverse Events (“**AEs**”) Grade 4 or higher that do not resolve within 360 days post-treatment; whereby:

- Grade 1 = Mild
- Grade 2 = Moderate
- Grade 3 = Severe
- Grade 4 = Life-threatening or disabling
- Grade 5 = Death

Press Release



Shawn Shirazi, Ph.D., CEO - Drug Division, Theralase stated that, “The UHN REB approval represents a major milestone for Theralase. I am pleased that the Phase II ACT-NMIBC study has been approved and UHN is able to commence enrolling and treating patients. The safety of the ACT technology for NMIBC has been validated in the Phase Ib clinical study, demonstrating strong efficacy at 66% CR albeit in a small sample size. We look forward to demonstrating to the medical community what the ACT technology is capable of accomplishing in a larger patient population. Finding improved therapies for BCG-Unresponsive NMIBC patient population is a critical unmet medical need.”

Kipton Lade, B.Sc., M.Sc., MBA, CEO - Device Division, Theralase stated that, “The Company has focused its engineering resources on upgrading the TLC-3200 medical laser system based on clinical feedback gained in the Company’s successfully completed Phase Ib study. We are excited to introduce this next level technology into the Phase II ACT-NMIBC study.”

About Theralase® Technologies Inc.

Theralase is a clinical stage pharmaceutical company dedicated to the research and development of light activated Photo Dynamic Compounds and their associated drug formulations intended to safely and effectively destroy various cancers.

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

This news release contains “forward-looking statements” which reflect the current expectations of management of the Company’s future growth, results of operations, performance and business prospects and opportunities. Such statements include, but are not limited to, statements regarding the Company’s proposed development plans with respect to Photo Dynamic Compounds and their drug formulations. Wherever possible, words such as “may”, “would”, “could”, “should”, “will”, “anticipate”, “believe”, “plan”, “expect”, “intend”, “estimate”, “potential for” and similar expressions have been used to identify these forward-looking statements. These statements reflect management’s current beliefs with respect to future events and are based on information currently available to management. Forward-looking statements involve significant risks, uncertainties and assumptions including with respect to the ability of the Company to: adequately fund, secure the requisite regulatory approvals to commence and successfully complete a Phase II NMIBC clinical study in a timely fashion and implement its development plans. Many factors could cause the Company’s actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements; including, without limitation, those listed in the filings made by the Company with the Canadian securities regulatory authorities (which may be viewed at www.sedar.com). Should one or more of these risks or uncertainties materialize or should assumptions underlying the forward looking statements prove incorrect, actual results, performance or achievements may vary materially from those expressed or implied by the forward-looking statements contained in this news release. These factors should be considered carefully and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in the press release are based upon what management currently believes to be reasonable assumptions, the Company cannot assure prospective investors that actual results, performance or achievements will be consistent with these forward-looking statements. The Company disclaims any intention or obligation to revise forward-looking statements whether as a result of new information, future developments or otherwise except as required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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For More Information:

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1.866.THE.LASE (843-5273) x304
416.699.LASE (5273) x304
Amelia Tudo, Investor Relations Coordinator
atudo@theralase.com
www.theralase.com