

Theralase Launches First Clinical Study Site in the US for Phase II Bladder Cancer Clinical Study

Toronto, Ontario – January 19, 2021, Theralase® Technologies Inc. (“**Theralase**” or the “**Company**”) (**TSXV: TLT**) (**OTCQB: TLTF**), a clinical stage pharmaceutical company focused on the research and development of light activated Photo Dynamic Compounds (“**PDC**”) and their associated drug formulations used to safely and effectively destroy various cancers, bacteria and viruses announced today that Virginia Urology (“**VU**”) has received site Institutional Review Board (“**IRB**”) approval to commence a pivotal phase II Non-Muscle Invasive Bladder Cancer (“**NMIBC**”) Clinical Study to enroll and treat patients with Bacillus Calmette Guerin (“**BCG**”)-Unresponsive Carcinoma In-Situ (“**CIS**”) or are intolerant to BCG Therapy (“**Study II**”).

Theralase has central IRB approval to launch a number of US clinical sites, subject to local site IRB approval. VU is the first site to receive both central and local site IRB approval. There are 5 additional US clinical study sites that have received central IRB approval and are expected to receive local IRB approval in 1Q2021.

VU has a long history of providing quality care to the Greater Richmond area since 1929. VU is comprised of 6 locations throughout the Greater Richmond area with over 55 board-certified physicians that span nearly every discipline within the field of urology. Because VU consists of diverse medical professionals, they are able to provide the latest technologies with a mission of providing the best possible care for each patient.

Dr. Eugene Kramolowsky II, M.D., a Urologic Oncologist at VU Research Department stated “We are excited to work with Theralase for the NMIBC clinical study. Tackling cancer is a crucial topic and a priority for this region, and I am pleased that Virginia Urology is able to contribute to the growth of innovative cancer research by taking part in this leading pivotal Photo Dynamic Therapy (“**PDT**”) study”.

To date 14 patients have been treated in Study II. With the addition of VU, the Company now has 5 clinical study sites open in Canada and 1 in the US for patient enrollment and treatment.

Shawn Shirazi PhD, Chief Executive Officer, Theralase®, stated, “We are excited to have central IRB approval, which will help expedite the launch of other US clinical study sites subject to local IRB approval. VU is now able to commence patient enrollment and treatment in the US. We look forward to increasing the number of patients enrolled and treated in Study II, as a result of launching additional clinical study sites in the US.”

About Study II

Study II utilizes the Therapeutic Dose (0.70 mg/cm²) of TLD-1433 and is focused on the enrollment and treatment of approximately 100 BCG-Unresponsive NMIBC CIS patients in up to 20 clinical study sites located in Canada and the US.

Study II has a:

- 1) Primary endpoint of efficacy (defined by Complete Response (“**CR**”) at any point in time
- 2) Secondary endpoint of duration of CR at 360 days post-initial CR (approximately 450 days post initial Study treatment, assuming CR is achieved at the 90 day assessment)
- 3) Tertiary endpoint of safety measured by incidence and severity of Adverse Events (“**AEs**”) grade 4 or higher that do not resolve within 450 days post-initial treatment

The FDA, in its 2018 guidance to industry has stated that, “For single-arm trials of patients with BCG-unresponsive disease, the FDA defines a CR as at least one of the following:

- 1) Negative cystoscopy and negative (including atypical) urine cytology
- 2) Positive cystoscopy with biopsy-proven benign or low-grade NMIBC and negative cytology
- 3) For intravesical therapies without systemic toxicity, the FDA includes, in the definition of a CR, negative cystoscopy with malignant urine cytology, if cancer is found in the upper tract or prostatic urethra and random bladder biopsies are negative.

Intravesical instillation does not deliver the investigational drug to the upper tract or prostatic urethra; therefore, the development of disease in these areas cannot be attributed to a lack of activity of the investigational drug. Thus, sponsors can consider patients with new malignant lesions of the upper tract or prostatic urethra, who have received intravesical therapy to have achieved a CR in the primary analysis; however, sponsors should record these lesions and conduct sensitivity analyses in which these patients are not considered to have achieved a CR.”¹

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, bacteria and viruses.

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

Forward Looking Statement:

This news release contains "forward-looking statements" which reflect the current expectations of the Company's management for future growth, results of operations, performance, 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 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 commercialization 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.

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

For More Information:

1.866.THE.LASE (843-5273)

416-699-LASE (5273)

www.theralase.com

Press Release



Kristina Hachey
Chief Financial Officer
khachey@theralase.com
416-699-LASE (5273) x 224

¹ "BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment – Guidance for Industry" Dated: February 2018