# Press Release

## Theralase Reports on Phase II Non-Muscle Invasive Bladder Cancer ("NMIBC") Clinical Study ("Study II") Progress

**Results of the First 12 patients enrolled in the Phase II NMIBC Clinical Study Demonstrate a 58.3% Response 90 Days Post Initial Treatment**

*Toronto, Ontario – July 30, 2020,* Theralase® Technologies Inc. ("**Theralase**" or the "**Company**") (**TSXV: TLT**) (**OTCQB: TLTFF**), a clinical stage pharmaceutical company focused on the research and development of light activated Photo Dynamic Compounds ("**PDC**") and their associated drug formulations to safely and effectively destroy various cancers is pleased to provide an update on its Phase II Non-Muscle Invasive Bladder Cancer ("**NMIBC**") Clinical Study ("**Study II**").

The primary purpose of Study II is to discover if the TLD-1433 ("**Study Drug**") combined with TLC-3200 ("**Study Device**") (collectively the "**Study Treatment**") are effective in the destruction of Bacillus Calmette-Guérin ("**BCG**")-Unresponsive Non-Muscle Invasive Bladder Cancer ("**NMIBC**").

All Canadian clinical study sites currently remain closed for new patient enrollment and treatment; however, Canadian clinical study sites, who have already enrolled and treated patients, are providing second treatments. The Company is preparing to launch a fifth Canadian clinical study site later in the year.

The Company is preparing to launch a number of US based clinical sites later in the year, subject to the United States economy recovering from COVID-19; however, it is anticipated due to the severity of the COVID-19 pandemic in the United States, that these sites will not be open to commence enrollment and treatment of patients until 2021.

Study II enrolled and treated 12 patients, with the following results:

| Patient Status | Number of Patients | Percentage |
|---|---|---|
| **First Treatment Provided** | 12 | 100.0% |
| **Patients Eligible to Receive Second Treatment** | 8 | 66.7% |
| **Second Treatment to be Provided** | 5 | 41.7% |
| **Second Treatment Provided** | 3 | 25.0% |
| | | |
| **Response at 90 Days Post Initial Treatment** | 7 | 58.3% |
| **Complete Response at 90 Days Post Initial Treatment** | 3 | 25.0% |
| | | |
| **Patients Removed from Study II** | 4 | 33.3% |

**Study II Interim Data Analysis:**

Of the 7 patients, who demonstrated a Response to the Study Treatment defined as negative cystoscopy (no evidence of cancer in their bladders) or negative urine cytology (no evidence of the urothelial carcinoma cells in their urine)) at 90 days post initial treatment:

- 43% achieved a Complete Response ("**CR**") (negative cystoscopy and negative urine cytology).
- 43% achieved a Response (negative cystoscopy and positive or suspicious cytology)
- 14% achieved a Response (suspicious cystoscopy and negative cytology)

The patients who responded to the Study Treatment are currently under medical review to assess the cause of the suspicious cystoscopy by directed bladder biopsy and the cause of the positive or suspicious cytology by repeating the urine cytology analysis. If found to be negative, these patients will be allocated to the CR column. If positive or suspicious again, then Computerized Tomography ("**CT**") Scan imaging and/or prostatic biopsies will be conducted to rule out Upper Tract Urothelial Cell Carcinoma ("**UTUCC**"). If UTUCC is proven to exist, then according to FDA's Bacillus Calmete Guérin ("**BCG**")-Unresponsive Guidelines to Industry, issued in February 2018, these patients will be classified as CR, as only the bladder was treated by the Study Treatment and not non-addressable areas of the urinary system.

Of the 4 patients that were removed from Study II, the clinical protocol in effect at the time stated in the patient withdrawal criteria that "Patients found to have at Day 90 new T1 high-grade disease, with or without CIS" and "Patients found to have unchanged or worsening CIS at 3 months" will be removed from Study II.

Of the 4 patients removed from the Study, they presented with "unchanged CIS at 3 months".

This was an oversight on behalf of the Company and the clinical protocol has since been updated to remove these two specific patient withdrawal criteria, maintaining the key patient withdrawal criteria of NMIBC progression, which includes "Progression to Muscle Invasive Bladder Cancer ("**MIBC**")" and "Progression to metastatic disease". These changes, had they been in place, would have led to the retreatment of these 4 patients and an opportunity to achieve CR for these patients at a later medical assessment point.

**Study Treatment Optimizations:**

Additional optimizations to the clinical study protocol that have been implemented for all future patients to be enrolled and treated in Study II and for the five patients yet to receive their second treatment, include:

**Bladder Volume Calculation:**

The clinical protocol did not clearly define the bladder volume calculation to be used by the pharmacy and the principal investigator to determine bladder size for administration of the Study Drug and Study Device, respectively. Average bladder volume voided over a 3 day period was used as opposed to a percentage of the maximum bladder volume voided.

**Study Device Treatment Time:**

The Study Device treatment time was based on detected bladder irradiance, which varied dramatically inside patient bladders due to shape, volume and bladder wall reflection. This led to undertreatment of certain patients with the Study Device by up to 87.9%. This has been modified to now determine Study Device treatment time based solely on the new bladder volume calculation, resulting in a more consistent Study Device treatment time across patients.

**Summary:**

The total of these Study II variances (Study Drug Volume, Study Device Volume and Study Device Treatment Time) have led to all 12 patients being undertreated by the Study Treatment from between 30.9% and 154.3%.

**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 patients presenting with Carcinoma In-Situ ("**CIS**") in approximately 20 clinical study sites located in Canada and the US.

Study II has a:

1) Primary endpoint of efficacy (defined by CR) at any point in time
2) Secondary endpoint of duration of CR at 360 days post-initial CR
3) Tertiary endpoint of safety measured by incidence and severity of Adverse Events ("**AEs**") grade 4 or higher that do not resolve within 360 days post-initial CR

"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, 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]

**Forward Looking Statement**

*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:**

# Press Release

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