

## Theralase<sup>®</sup> Phase Ib NMIBC Clinical Study Published

TORONTO, June 21, 2022 -- Theralase<sup>®</sup> Technologies Inc. ("Theralase" or the "Company") (TSXV: TLT) (OTCQB: TLTF), 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 is pleased to announce that Theralase<sup>®</sup>'s Phase Ib Non-Muscle Invasive Bladder Cancer ("NMIBC") clinical study ("Study") has been peer reviewed and published in the European Urology Open Science ("EUOS") Journal, Volume 41, July 2022.

According to EUOS's website, EUOS is dedicated to the publication of high quality, innovative research that will benefit patients with urological conditions. EUOS covers research in the urological field, including clinical, basic and translational research.

The publication can be accessed online at no charge at:

<https://www.sciencedirect.com/science/article/pii/S2666168322005900>

The publication states, "Despite efforts to bring new treatment strategies forward for Bacillus Calmette Guérin ("BCG")-Unresponsive NMIBC, a clear consensus for a standard treatment other than [radical cystectomy](#) has yet to be established. An effective therapy that provides a high initial and durable responses remains an unmet need."

The publication is entitled, "A Phase 1b Clinical Study of Intravesical Photodynamic Therapy in Patients with Bacillus Calmette-Guérin-unresponsive Non-muscle-invasive Bladder Cancer" and states, "Although limited by the small sample size typically inherent in phase 1 trials, we feel that the photosensitizer TLD-1433 and the delivery device TLC-3200 hold promise for the treatment of NMIBC. In this study, Photo Dynamic Therapy ("PDT") was well tolerated and demonstrated safety and potential efficacy, thus warranting further study."

As a result, the Medical and Scientific Advisory Board ("MSAB") unanimously agreed that Theralase<sup>®</sup> should further investigate PDT in a multi-site, pivotal Phase II NMIBC Clinical Study ("Study II"). Study II is currently underway at 5 Clinical Study Sites ("CSS") in Canada and 7 CSSs in the United States, with 41 patients treated to date.

Girish Kulkarni, M.D., Ph.D., lead principal investigator of the Study at the Divisions of Urology and Surgical Oncology, Department of Surgery, Princess Margaret Cancer Centre, University Health Network, University of Toronto, Toronto, Ontario, Canada ("UHN") stated, "I am delighted that the high-quality research conducted at UHN, in conjunction with Theralase<sup>®</sup>, was successful, in this challenging patient population, both for safety and potential efficacy. Patients with BCG-Unresponsive NMIBC are a difficult patient population to treat since they have unfortunately failed the standard of care, BCG. Many also failed other investigational therapies prior to being treated with Theralase<sup>®</sup>'s PDT. The clinical data that we collected was robust and clinically relevant. I am fully supportive of the multi-site Phase II NMIBC clinical study, currently in progress, to further investigate the role of PDT in BCG-Unresponsive NMIBC."

Dr. Arkady Mandel M.D., Ph.D., D.Sc., Interim Chief Executive Officer and Chief Scientific Officer of Theralase<sup>®</sup> stated, "The Company is very pleased to share the Study clinical data that has been peer-reviewed and published in EUOS. Indeed, the publication of clinical results in a peer reviewed journal like EUOS validates the quality of the Theralase<sup>®</sup> research and the professionalism of the clinical study team, who conducted it. As a direct result of the success of this initial Study, Theralase<sup>®</sup> elected to undertake Study II, which I am happy to report is proceeding well. I am encouraged by the clinical data generated to date with intravesical TLD-1433, activated by laser light therapy, as I believe Theralase<sup>®</sup>'s PDT is a viable alternative for the BCG-Unresponsive NMIBC patient population, although significant data is still pending. The ongoing analysis of the patients supports that up to 50% of evaluable patients (patients who have been clinically assessed by the principal investigators at study visits and whose response to a treatment can be measured because enough information has been collected) have achieved the primary study objective. We are grateful for the ongoing support to all clinical and technical personnel involved in the successful completion of the Study and in the strong clinical data collected to date for Study II. Based on the strength of the clinical data collected and the consistently high safety and efficacy profile of Theralase<sup>®</sup>'s PDT, I am confident that TLD-1433-based therapy has the potential to become the next gold-standard in the treatment of BCG-Unresponsive patients."

### About Study I

The Study's primary objective was safety and tolerability of PDT, with a secondary objective of pharmacokinetics (drug evacuation from the body) and a tertiary objective of efficacy (CR primarily at 90 and secondarily at 180 days for patients treated at the maximum recommended starting dose (0.35 mg/cm<sup>2</sup>) and the therapeutic dose (0.70 mg/cm<sup>2</sup>)). Patients who were treated at the therapeutic dose, consented to be followed clinically for 18 months, post initial treatment.

### About Study II

Study II utilizes the therapeutic dose of TLD-1433 (0.70 mg/cm<sup>2</sup>) activated by the proprietary TLC-3200 medical laser system. Study II is focused on enrolling and treating approximately 100 to 125 BCG-Unresponsive NMIBC Carcinoma In-Situ ("CIS") patients in up to 15 CSSs located in Canada and the United States.

## **Study II Objectives:**

- **Primary** - Efficacy (defined by CR) at any point in time.
- **Secondary** - Duration of CR (defined by duration of CR lasting a minimum 360 days post-initial CR).
- **Tertiary** - Safety measured by incidence and severity of AEs Grade 4 or higher that do not resolve within 450 days post primary study treatment. (Grade 1 = Mild, Grade 2 = Moderate, Grade 3 = Serious, Grade 4 = Life Threatening and Grade 5 = Death)

## **About TLD-1433**

TLD-1433 is a patented PDC with over 10 years of published peer-reviewed preclinical and clinical research and is currently under investigation in Study II.

## **About Theralase® Technologies Inc.**

Theralase® is a clinical stage pharmaceutical company dedicated to the research and development of light activated compounds and their associated drug formulations with a primary objective of efficacy and a secondary objective of safety in the destruction of various cancers, bacteria and viruses.

Additional information is available at [www.thermalase.com](http://www.thermalase.com) and [www.sedar.com](http://www.sedar.com)

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## **Forward Looking Statements**

*This news release contains "forward-looking statements" within the meaning of applicable Canadian securities laws. 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. Forward looking statements may be identified by the use of the words "may", "should", "will", "anticipates", "believes", "plans", "expects", "estimate", "potential for" and similar expressions including statements related to the current expectations of Company's management for future research, development and commercialization of the Company's Photo Dynamic Compounds and their drug formulations, including preclinical research, clinical studies and regulatory approvals.*

*These statements involve significant risks, uncertainties and assumptions; including, the ability of the Company to: adequately fund and secure the requisite regulatory approvals to successfully complete a Phase II NMIBC clinical study in a timely fashion to implement its development plans. Other risks include: the ability of the Company to successfully commercialize its drug formulations, the risk that access to sufficient capital to fund the Company's operations may not be available or may not be available on terms that are commercially favorable to the Company, the risk that the Company's drug formulations may not be effective against the diseases tested in its clinical studies, the risk that the Company's fails to comply with the term of license agreements with third parties and as a result loses the right to use key intellectual property in its business, the Company's ability to protect its intellectual property, the timing and success of submission, acceptance and approval of regulatory filings, and the impacts of public health crises, such as COVID-19. Many of these factors that will determine actual results are beyond the Company's ability to control or predict.*

*Readers should not unduly rely on these forward-looking statements which are not a guarantee of future performance. There can be no assurance that forward looking statements will successfully come to fruition, as such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results or future events to differ materially from 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.*

*All forward-looking statements are made as of the date hereof and are subject to change. Except as required by law, the Company assumes no obligation to update such statements.*

## **For More Information:**

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