

Health Canada Approves Amended Clinical Trial Application

Toronto, Ontario – June 26, 2019, Theralase® Technologies Inc. ("**Theralase**" or "**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, announced today that Health Canada has issued a No Objection Letter ("**NOL**") for an amended Clinical Trial Application ("**CTA**") for its Phase II Non-Muscle Invasive Bladder Cancer ("**NMIBC**") clinical study ("**Phase II Study**").

The amended CTA was submitted to Health Canada to update the current CTA, for an optimized design of the TLC-3200 medical laser system ("**Study Device**") and is subject to Investigational Testing Authorization ("**ITA**") by Health Canada and Review Ethics Board ("**REB**") approval by each Study II site before being used in the Phase II Study. The amended CTA will not impede the Phase II Study as patients will continue to be treated with the Study Drug and Study Device under the current CTA, ITA and REB approvals until the Company receives the new ITA and REB approvals.

The Study Device will be used to activate the PDC TLD-1433 ("**Study Drug**") in the bladder in the Phase II Study.

Study Device optimizations, include:

- 1) A more powerful laser engine (reduces patient treatment times)
- 2) Higher precision and repeatability in laser light detection (higher patient efficacy)
- 3) Increased robustness in laser power capacity and operator handling (higher patient safety)
- 4) Reduced physical size allowing for the use of a flexible cystoscope (higher patient safety)
- 5) An ability to detect laser emitter movement during the Study Procedure (higher patient safety)
- 6) An optimized graphical user interface and system feedback control to allow the principal investigator to operate an "on-off" operation to deliver an effective Study II treatment

Shawn Shirazi, Ph.D., CEO - Drug Division, Theralase stated that, "A new CTA was submitted to Health Canada in order to provide updates to the Phase II Study clinical protocol, which included optimizations of the Study Device. Receipt of the NOL from Health Canada is subject to receipt of a pending ITA by Health Canada and REB approval from each clinical study site that will participate in the Phase II study, will allow the Company to supply these study sites with the most optimized, technologically advanced Study Device. In the interim, prior to these approvals, our primary study site is actively enrolling patients and if a patient were to be scheduled for treatment, prior to the new ITA and REB approval, they could effectively be treated with the Study Drug and Study Device currently under CTA, ITA and REB approval. This is a significant milestone for the Company, as we continuously strive to bring the most advanced technology to the clinical sites to provide safer and more effective technology in the treatment of their patients."

Dr. Shirazi continued by stating, "Theralase is currently working to register up to an additional 19 clinical study sites this year, subject to regulatory and clinical study site approvals. The study sites include Canadian, US and European Union oncology institutions. Registration of the US and EU clinical study sites, will be subject to the filing and regulatory approval of our Phase II study by the US FDA and European Medicines Agency regulatory authorities. Theralase has a patented Study Drug and Study Device that

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when combined, have proven to be safe and effective in the treatment of patients inflicted with Bacillus Calmette Guérin-Unresponsive NMIBC. Our primary focus is and remains the successful completion of this pivotal Phase II study; however, the Company, through Arkady Mandel, MD, PhD, DSc, Chief Scientific Officer of Theralase continues to research and develop our PDCs for the treatment of other oncological indications, such as Glioblastoma Multiforme (“GBM”), Non-Small Cell Lung Cancer (“NSCLC”) and most recently non-melanoma related skin cancer.”

Kipton Lade, B.Sc, M.Sc. MBA, CEO - Device Division, Theralase stated that, “The Company is pleased that it was able to execute on the scope of engineering improvements to the TLC-3200, without impeding the Phase II Study. Our internal and external engineering teams have optimized the Study Device to enhance outpatient treatments, through both hardware and software upgrades, allowing:

- 1) Shorter patient treatment times
- 2) Increased patient efficacy
- 3) Increased patient safety

We hope that these optimizations translate into a successful completion of the Phase II clinical study for the Company and potentially in the future allow patient treatments to be performed in a non-operating room environment.”

About Glioblastoma Multiforme

There are an estimated 24,000 new cases of malignant gliomas diagnosed in the US annually, with more than 17,000 deaths.¹ In the majority of cases, they recur following initial treatment, especially for GBM, the most common and lethal form of brain cancer. Most patients do not survive beyond 2 years, post diagnosis.²

About Non-Small Cell Lung Cancer

Lung cancer is by far the leading cause of cancer death among both men and women.³ Out of all types of lung cancer, NSCLC accounts for 80 to 85% of cases.⁴ The American Cancer Society’s estimates for lung cancer in the United States for 2019 are approximately, 228,150 new cases of lung cancer, and approximately 142,670 deaths from lung cancer.³

About Non-Melanoma Skin Cancer:

One in five Americans will develop skin cancer by the age of 70.⁵ More people are diagnosed with skin cancer each year in the U.S. than all other cancers combined.⁶ More than 5.4 million cases of non-melanoma skin cancer were treated in over 3.3 million people in the U.S. in 2012.⁷ The annual cost of treating skin cancers in the U.S. is estimated at \$8.1 billion: about \$4.8 billion for non-melanoma skin cancers and \$3.3 billion for melanoma.⁸

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.

¹ Baylor College of Medicine. (2017, March 27). New genetic risk factors identify two distinct glioma subtypes. *ScienceDaily*. Retrieved June 22, 2019 from www.sciencedaily.com/releases/2017/03/170327114356.htm

² Kamiya-Matsuoka, C., & Gilbert, M. R. (2015). Treating recurrent glioblastoma: an update. *CNS oncology*, 4(2), 91–104. doi:10.2217/cns.14.55

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³ American Cancer Society. (2019). *Key Statistics for Lung Cancer*. [online] Available at: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/key-statistics.html> [Accessed 24 Jun. 2019].

⁴ American Cancer Society. (2019). *What Is Non-Small Cell Lung Cancer?*. [online] Available at: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html> [Accessed 24 Jun. 2019].

⁵ Stern, RS. Prevalence of a history of skin cancer in 2007: results of an incidence-based model. *Arch Dermatol* 2010; 146(3):279-282.

⁶ *Cancer Facts and Figures 2019*. American Cancer Society. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html>. Accessed January 14, 2019.

⁷ Rogers HW, Weinstock MA, Feldman SR, Coldiron BM. Incidence estimate of nonmelanoma skin cancer (keratinocyte carcinomas) in the US population, 2012. *JAMA Dermatol* 2015; 151(10):1081-1086.

⁸ Guy GP, Machlin SR, Ekwueme DU, Yabroff KR. Prevalence and costs of skin cancer treatment in the U.S., 2002-2006 and 2007-2011. *Am J Prev Med* 2015; 48(2):183-187. doi: 10.1016/j.amepre.2014.08.036.

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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