



Destroying Cancer at the Speed of Light®

October 15, 2024

TSXV:TLT | OTCQB:TLTFF

# Forward-Looking Statements

Forward-Looking Statements (“**FLS**”) contained in this presentation deal with the future revenue potential, business opportunities and/or strategic initiatives of Theralase® Technologies Inc. (“**Theralase**” or the “**Company**”); including, information, analyses and/or projections as to future corporate developments that reflect the current expectations of the Company’s management.

Such FLS, refer to the Company’s ongoing preclinical, clinical and/or medical device research and development efforts; including, but not limited to assumptions about Theralase®’s: business operations, continued performance on a basis consistent with prior years; ability to access financing from time to time on favourable terms, or at all; ability to retain executive management, senior management, key personnel and/or key consultants or the non-disruptive replacement of them on reasonable terms; reasonably stable operating and/or general administrative expenses; future success of current or proposed research and development initiatives, achievement of commercialization activities and/or milestones; market success of its products over its competition; successful and timely achievement of regulatory, marketing and/or certification approvals; uncontested protection over its intellectual property in the markets in which it does business; market acceptance and/or revenue generation of its products; operation in stable economic environments (Canada, the United States and internationally); ability to access currency, exchange rates, interest rates and/or commodity prices at reasonable rates.

No conclusions as to the successful outcome of the ongoing and planned research and development initiatives in which the Company is involved are intended or implied; nor can they be foreseen or predicted prior to definitive corporate announcements as to their outcome. Any statements that refer to expectations, projections, future events or achievement of strategic initiatives are FLS. Although Theralase®’s management believes that the expectations reflected in any FLS made in this presentation are reasonable, such statements are based on a number of assumptions, which may prove to be incorrect; including, but not limited to assumptions related to the risks and factors set out in the Company’s current Annual Information Form (“**AIF**”) and documentation available on SEDAR under the Company’s profile at [www.sedar.com](http://www.sedar.com). Accordingly, no assurances can be given that any of the events or circumstances contemplated by such FLS will transpire or occur or, if any of them transpire or occur, what impact they will have on Theralase®’s results of operations or financial condition. Furthermore, the FLS contained in this presentation are made as of the date hereof for the purpose of providing, potential investors with information regarding the Company’s future plans for its business and expected milestones. The Company does not undertake any obligation to update publicly or to revise any of the included FLS, whether as a result of new information, future events or otherwise, unless as required by applicable laws. The FLS contained in this presentation are expressly qualified by this cautionary statement.

The Company’s financial disclosure includes non-International Financial Reporting Standards (“**IFRS**”) financial measures as supplemental indicators of the Company’s financial and operating performance. The Company believes these supplemental financial measures reflect the Company’s on-going business in a manner that allows for meaningful period-to-period comparisons and analyses of trends in its business. Accordingly, the Company believes that such financial measures may also be useful to potential investors in enhancing their understanding of the Company’s operating or future performance. These non-IFRS measures are not recognized under IFRS and do not have standardized meanings prescribed by IFRS; therefore, it is unlikely that these measures will be comparable to similarly titled measures reported by other issuers. Non-IFRS financial measures should be considered in the context of the Company’s IFRS results. The Company cautions readers to consider these non-IFRS financial measures, in addition to, and not as an alternative for, measures calculated in accordance with IFRS. The financial statements of the Company are prepared in accordance with IFRS and are reported in Canadian dollars. All currency amounts in this presentation and all references incorporated are expressed in Canadian dollars, unless otherwise indicated.

The material contained in this document is strictly confidential and the sole property of Theralase®. This presentation does not, and shall not, in any circumstances, constitute an offer to sell or solicitation of an offer to buy any securities of Theralase®, in any jurisdiction.

# Theralase® Strategic Objectives

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## 4Q2024

- Secure \$CAN 5 to 10M in equity financing (completion of Phase II registration clinical study)
- Receive Ontario Securities Commission receipt for a \$CAN 100M base shelf prospectus (raise subsequent funds based on achieving milestones)
- Achieve Break Through Designation (“**BTD**”) approval from the FDA

## 1Q2025

- Enroll remaining patients in Phase II bladder cancer registration clinical study (“**Study II**”) (75 patients enrolled and treated to date)

## 4Q2025

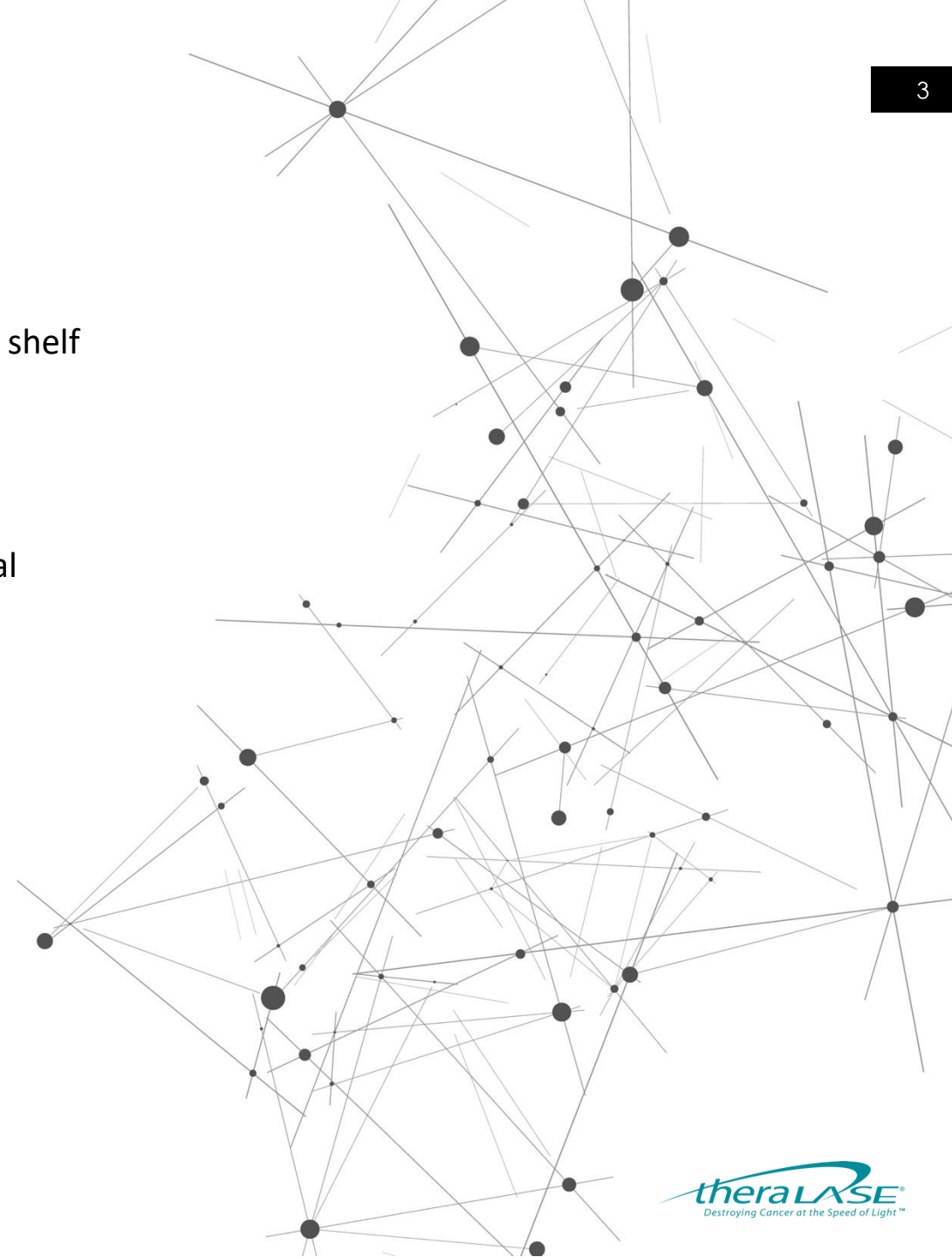
- Achieve FDA accelerated approval

## 2Q2026

- Soft and hard data lock of Study II

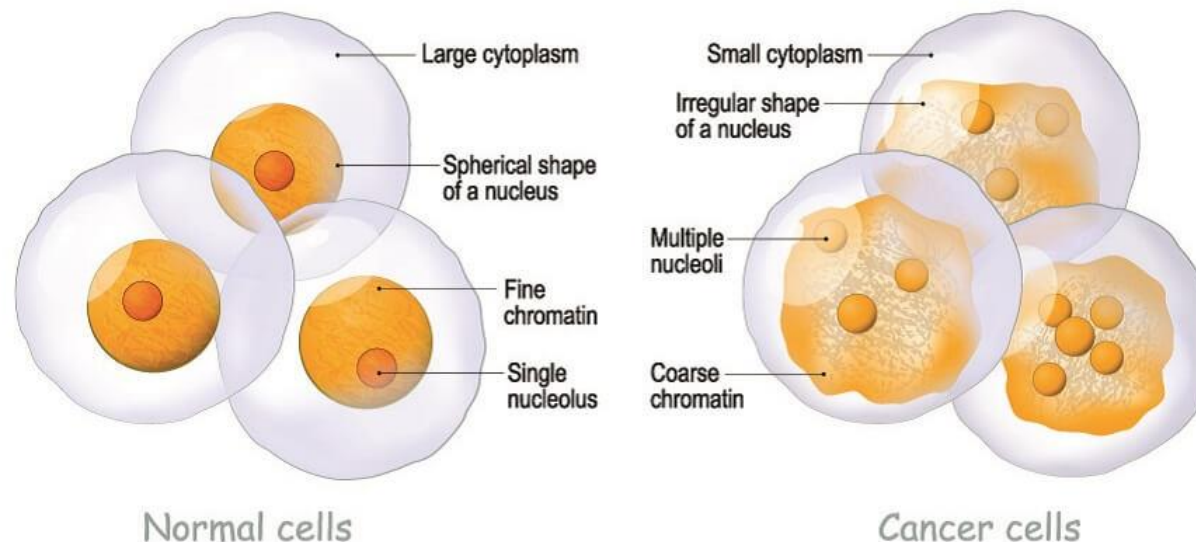
## 4Q2026

- Receive Health Canada and FDA marketing approval of Study II for commercial distribution in Canada and the United States

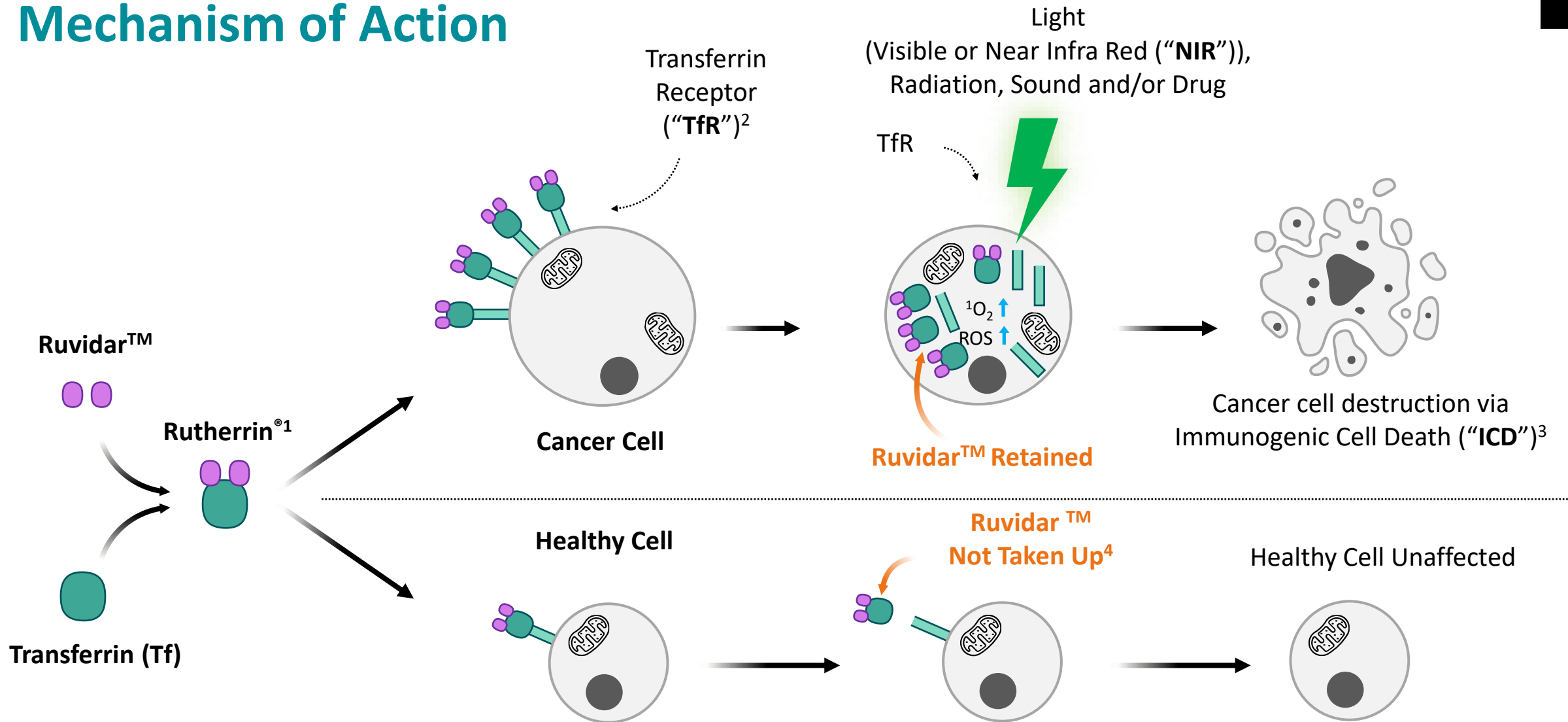


# What is Cancer?

- Cancer occurs when cells sustain DNA damage and become immortal.
- Normal cells grow - then die - when given signals to do so.
- Cancer cells ignore these signals and continue to multiply, leading to tumours and eventually death, if not destroyed.
- Each human has approximately 30 trillion cells in our bodies (200 different types, leading to over 100 known types of cancer).
- All cells require iron to grow. Since cancer cells grow at a much higher rate than healthy cells, they require significantly more iron, which is absorbed through their greater number of transferrin receptor sites.
- Theralase® uses this mechanism to target cancer cells versus health cells.



# Mechanism of Action



1) Kaspler P, Lazic S, Forward S, Arenas Y, Mandel A, Lilge L. A ruthenium(ii)based photosensitizer and transferrin complexes enhance photo-physical properties, cell uptake, and photodynamic therapy safety and efficacy. Photochem Photobiol Sci. 2016 Apr;15(4):481-95. doi: 10.1039/c5pp00450k. Epub 2016 Mar 7. PubMed PMID: 26947517

2) Jeong SM, Hwang S, Seong RH. Transferrin receptor regulates pancreatic cancer growth by modulating mitochondrial respiration and ROS generation. <https://doi.org/10.1016/j.bbrc.2016.02.023>

3) Kawamoto M., Horibe T., Kohno M., Kawakami K. A novel transferrin receptor-targeted hybrid peptide disintegrates cancer cell membrane to induce rapid killing of cancer cells. BMC Cancer. 2011; 11: 359

4) Seymour GJ, Walsh MD, Lavin MF, Strutton G, Gardiner RA. Transferrin receptor expression by human bladder transitional cell carcinomas. Urol Res. 1987;15(6):341-4. doi: 10.1007/BF00265663. PMID: 3324443.



## Scientific Research

Small molecule researched and developed over the last 20 years

Optimized to destroy cancer, bacteria and viruses, while sparing healthy cells<sup>1</sup>



## Pipeline

**Primary**  
Non-Muscle Invasive Bladder Cancer (“**NMIBC**”)<sup>2</sup>

**Secondary**  
Glioblastoma Multiforme (“**GBM**”)<sup>3</sup>

Non-Small Cell Lung Cancer (“**NSCLC**”)<sup>4</sup>

Vaccine for various enveloped viruses<sup>5</sup>



## Clinical Stage

Phase II NMIBC registration clinical study interim clinical data (75 patients treated, 68 evaluable patients):

60.3% Complete Response (“**CR**”) for the primary objective<sup>6</sup>

26.5% CR duration for the secondary objective<sup>6</sup>

Very high safety profile for the tertiary objective (n=68 patients)<sup>6</sup>

FDA Fast Track Designation Granted<sup>7</sup>



## Management Team

Extensive preclinical and clinical research, pharmaceutical drug, laser design, manufacturing and commercialization experience<sup>1</sup>

Partnered with leading scientific and clinical researchers from renowned research hospitals<sup>1</sup>



## Intellectual Property

28 issued patents and 17 patents pending for PDC and laser technology in the United States, Canada and internationally<sup>1</sup>

Composition of matter patent expires in US in 2033 (Potentially 2038 with extension)

1) Annual Information Form – September 20, 2023

2) Press Release - Theralase Commences Phase II NMIBC Clinical Study – April 25, 2019

3) Press Release - Theralase® Demonstrates Significant Advantage in Treatment of Brain Tumours – June 11, 2018

4) Press Release - Theralase® Advances Anti-Cancer Technology in Destruction of Human Lung Cancer– March 5, 2018

5) Press Release - February 7, 2022 – Theralase® Demonstrates Proof-of-Concept for Canadian-Made COVID-19 Vaccine

6) Press Release - Theralase® Releases 2Q2024 Financial Statements – October 7, 2024

7) Press Release - Theralase® Granted FDA Fast Track Designation for NMIBC Phase II Clinical Study – November 23, 2020



# Bladder Cancer

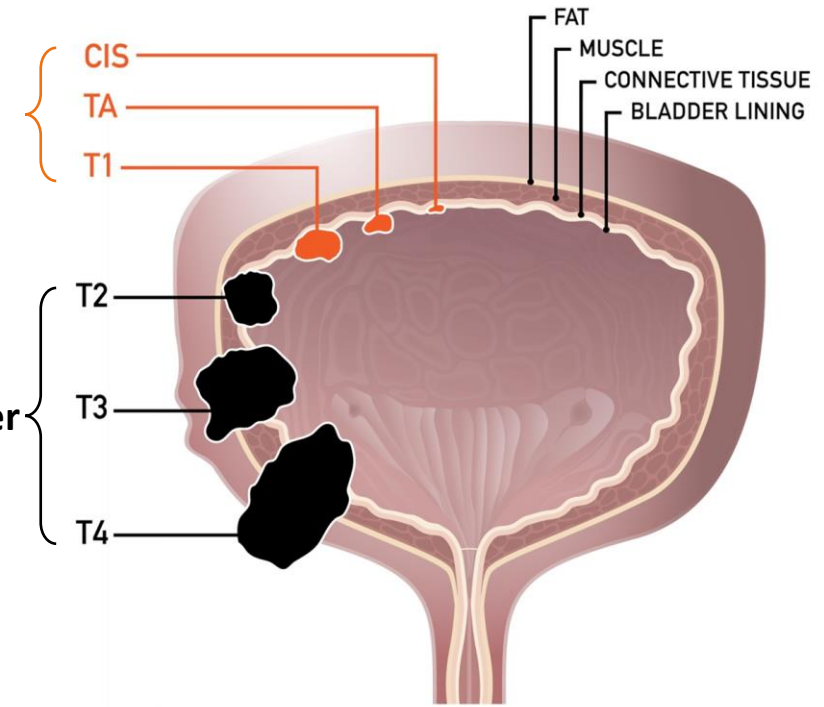
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10<sup>th</sup> Most Common Cancer Worldwide

6<sup>th</sup> and 17<sup>th</sup> most common cancer in men and women, respectively <sup>1</sup>

**Non-Muscle Invasive Bladder Cancer ("NMIBC")**

**Muscle Invasive Bladder Cancer ("MIBC")**



614,298 new cases of bladder cancer per year worldwide in 2022 <sup>1</sup>

83,190 in US, 15,111 in Canada, 204,000 in Europe <sup>2,3, 4</sup> (Total: 302,301)

1) World Cancer Research Fund International. Bladder cancer statistics. [www.wcrf.org/cancer-trends/bladder-cancer-statistic](http://www.wcrf.org/cancer-trends/bladder-cancer-statistic)

2) National Cancer Institute. Surveillance, Epidemiology and End Results Program. Cancer Stat Facts: Bladder Cancer. <https://seer.cancer.gov/statfacts/html/urinb.html>

3) Key Statistics for Bladder Cancer – American Cancer Society (2024); Canadian Cancer Society (2022) and Bladder Cancer – European Cancer Patient Coalition (2019)

4) International Agency for Research on Cancer. World Health Organization. Population Factsheets - [Cancer Today \(iarc.fr\)](http://cancer-today.iarc.fr)

# Current Treatment Landscape

- Bacillus Calmette Guérin (“**BCG**”) - standard of care treatment for NMIBC
- 75 to 80% of bladder cancers classified as NMIBC<sup>1,2</sup> and 10% of bladder cancers classified as Carcinoma In-Situ (“**CIS**”)<sup>2</sup>
- High initial efficacy BCG up to 70%<sup>2,3</sup> (30% failure rate)
- BCG is not durable<sup>4,5</sup> - 50% of BCG treated patients recur within 1 year<sup>6</sup> (BCG-Unresponsive<sup>5</sup>)
- 40% patients progress from BCG-Unresponsive CIS to MIBC within 5 years<sup>7,8,9</sup>
- 50% of patients who progress, develop metastatic disease, resulting in death in nearly all cases
- Radical cystectomy is the current standard of care for BCG-Unresponsive CIS

**“There is a critical need for effective bladder-sparing therapies for BCG-Unresponsive NMIBC”<sup>10</sup>**

1) Ripoll, J., Ramos, M., Montaña, J. et al. Cancer-specific survival by stage of bladder cancer and factors collected by Mallorca Cancer Registry associated to survival. BMC Cancer 21, 676 (2021). <https://doi.org/10.1186/s12885-021-08418-y><https://seer.cancer.gov/statfacts/html/urinb.html>(accessed 04-Dec-2019)

2) High-risk nonmuscle invasive bladder cancer - Mayo Clinic - 2021

3) Tang DH, Chang SS. Management of carcinoma in situ of the bladder: best practice and recent developments. Ther Adv Urol. 2015 Dec;7(6):351-64. doi: 10.1177/1756287215599694. PMID: 26622320; PMCID: PMC4647140. Steinberg RL, et al. Bladder Cancer 2015;1:105-126

4) Nepple KG et al. J Urol. 2010 Nov; 184:1915-1919

5) Hussain MHA. J Clin Oncol. 2009;27:5680-5684

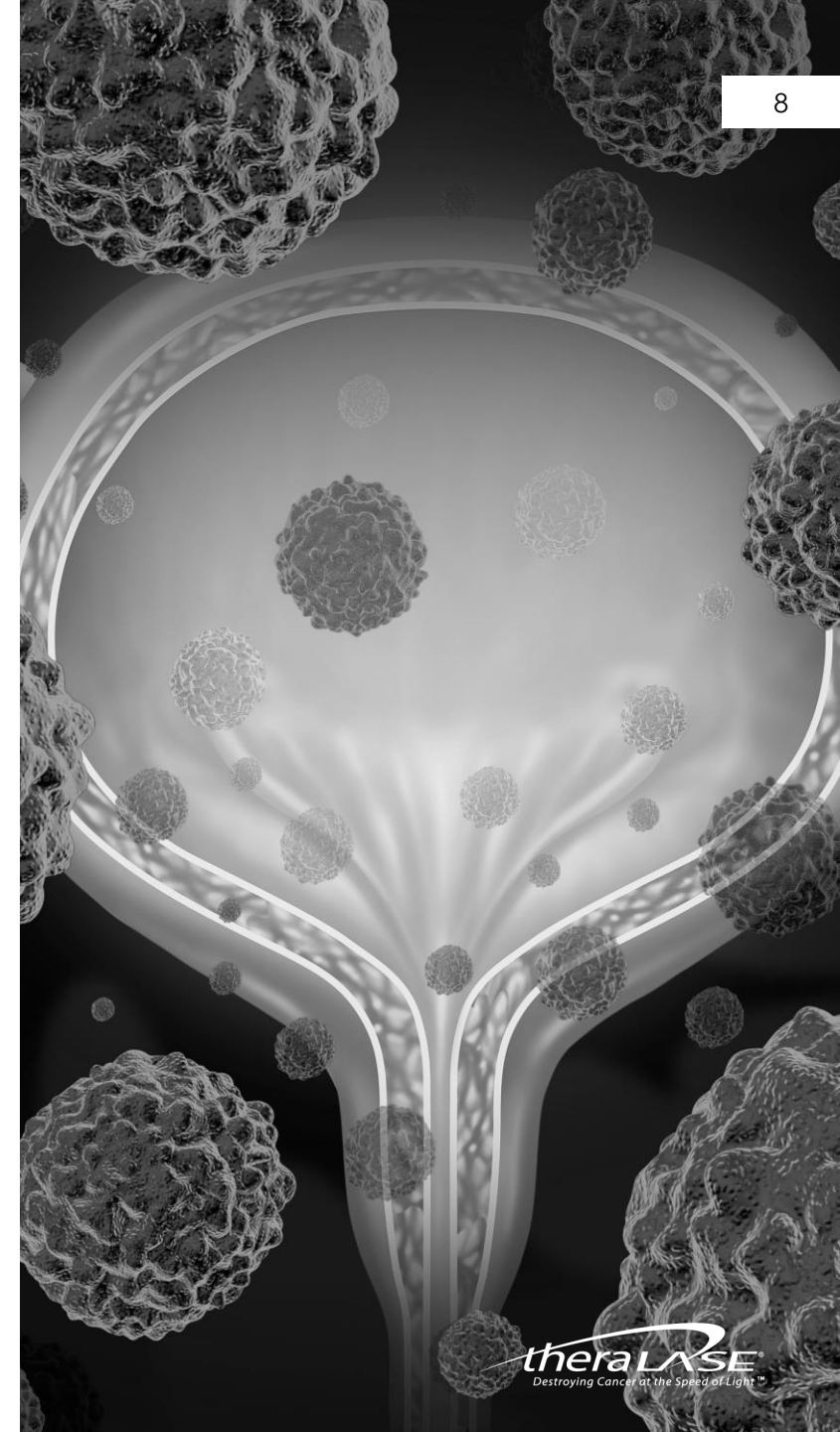
6) Chanâg SS. AUA/SUO guideline [manuscript]. 2016

7) Hussain MHA. J Clin Oncol. 2009;27:5680-5684

8) van den Bosch S. Eur Urol. 2011;60:493-500

9) Kamat AM, et al. Lancet 2016;388:2976-2810

10) Li R, Sundi D, Zhang J, Kim Y, Sylvester RJ, Spiess PE, Poch MA, Sexton WJ, Black PC, McKiernan JM, Steinberg GD, Kamat AM, Gilbert SM. Systematic Review of the Therapeutic Efficacy of Bladder-preserving Treatments for Non-muscle-invasive Bladder Cancer Following Intravesical Bacillus Calmette-Guérin. Eur Urol. 2020 Sep;78(3):387-399. doi: 10.1016/j.eururo.2020.02.012. Epub 2020 Mar 4. PMID: 32143924; PMCID: PMC7771323.



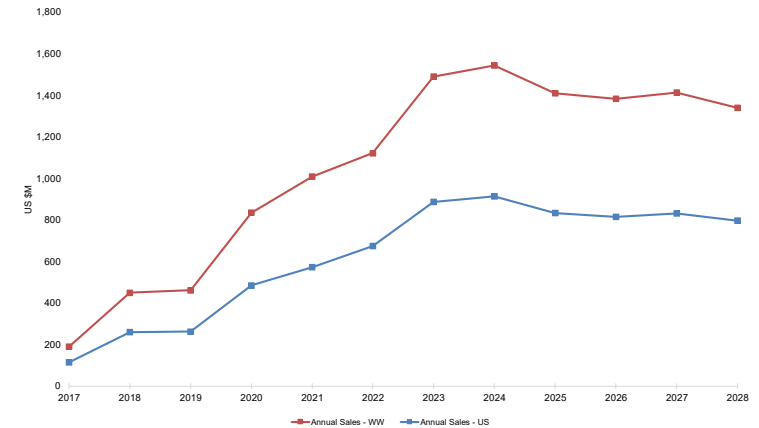


# Global Market Opportunity

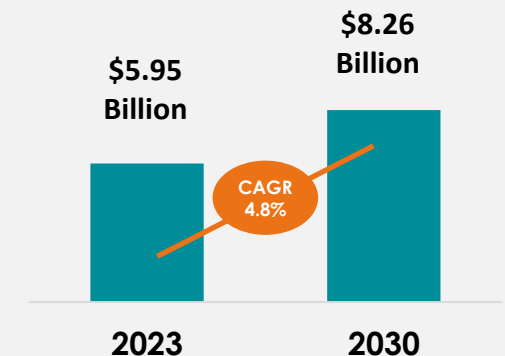
**$39,929^6 \times \$200,000^1 = \$8 \text{ Billion Annually}$**

- Patients willing to pay between \$USD 50k to \$USD 150k per Quality Adjusted Life Year (“**QALY**”) for treatment (2 Years = \$USD 100k to \$USD 300k (Average = \$USD 200k)<sup>1</sup>
- Bladder cancer patients face poor Quality of Life after radical cystectomy - high morbidity and high mortality<sup>2</sup>
- From diagnosis to death, it costs between \$USD 89,000 to \$200,000 to treat a bladder cancer patient<sup>3</sup>
- Bladder cancer has the highest lifetime treatment costs per patient of all cancers<sup>4</sup>

## KEYTRUDA Sales - Bladder Cancer<sup>7</sup>



## Global Bladder Cancer Market<sup>5</sup>



1) Willingness to pay per QALY for competitor drug, Pembrolizumab. Source: Cost-effectiveness of Pembrolizumab in Second-line Advanced Bladder Cancer, July 2018

2) Tyson MD 2nd, Barocas DA. Quality of Life After Radical Cystectomy. Urol Clin North Am. 2018 May;45(2):249-256. doi: 10.1016/j.ucl.2017.12.008. Epub 2018 Feb 21. PMID: 29650140.

3) Sievert KD, Amend B, Nagele U, et al. Economic aspects of bladder cancer: what are the benefits and costs?. World J Urol. 2009;27(3):295-300. doi:10.1007/s00345-009-0395-z

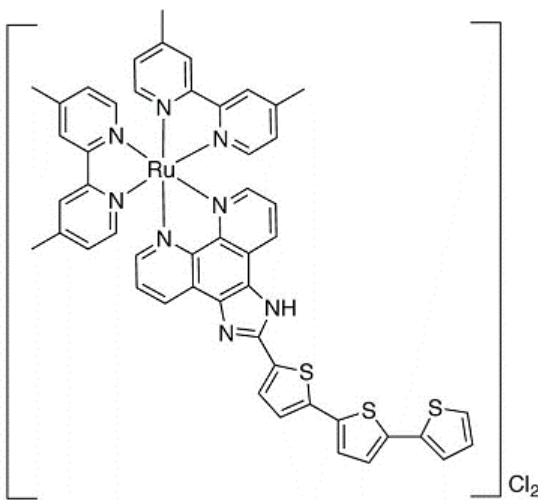
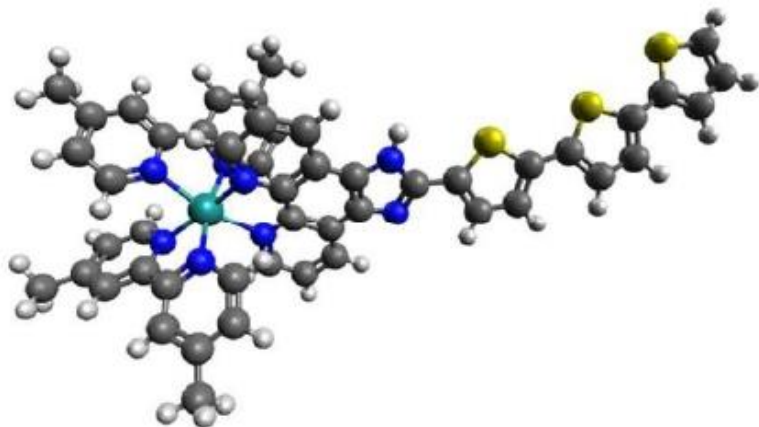
4) Ida K, Miyake M, Murakami K et al. Bacillus Calmette-Guérin-unresponsive non-muscle invasive bladder cancer outcomes in patients without radical cystectomy. Int J Clin Oncol. 2021 Nov;26(11):2104-2112. doi: 10.1007/s10147-021-01988-8. Epub 2021 Jul 27. PMID: 34313904

5) Bladder Cancer Market: Global Industry Analysis and Forecast (2024 -2030). Maximize Market Research. March 2024

6) World Cancer Research Fund International. Bladder cancer statistics. [www.wcrf.org/cancer-trends/bladder-cancer-statistic](http://www.wcrf.org/cancer-trends/bladder-cancer-statistic). (614,298 x 10% CIS x (30% Initial Failure Rate + (70% x 50% recurrence))) = 39,929)

# Ruvidar™ (TLD-1433)

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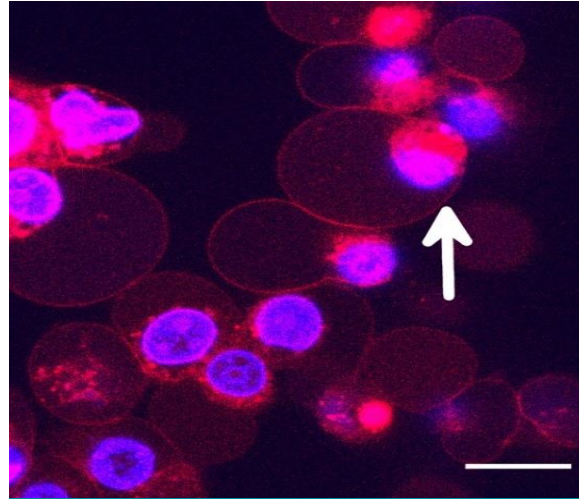
- Ruthenium based small molecule
- Designed to destroy solid core tumours (i.e.: bladder, brain, lung and breast) when absorbed by the cancer cell
- Activity is significantly enhanced when energy activated <sup>1</sup>
- Good Manufacturing Practices (“**GMP**”) manufactured in kilogram batches with high yield and high purity (98%)
- < 0.5 grams used for NMIBC Study Treatment

1) Kaspler P, Lazic S, Forward S, Arenas Y, Mandel A, Lilge L. A ruthenium(ii)based photosensitizer and transferrin complexes enhance photo-physical properties, cell uptake, and photodynamic therapy safety and efficacy. Photochem Photobiol Sci. 2016 Apr;15(4):481-95. doi: 10.1039/c5pp00450k. Epub 2016 Mar 7. PubMed PMID: 26947517

# Study Treatment



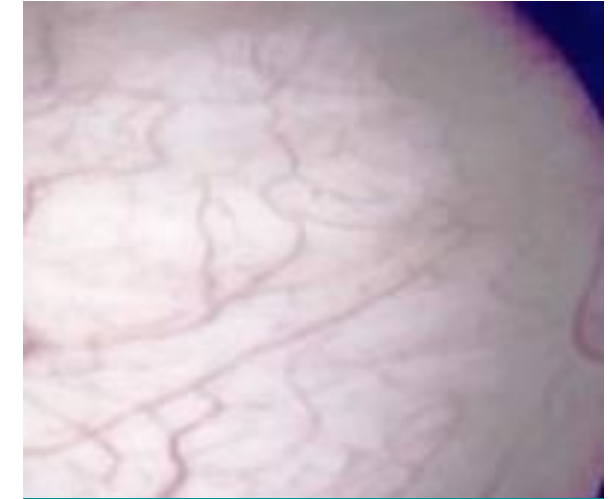
Ruvidar™ instilled  
in bladder via catheter  
demonstrating  
absorption into CIS <sup>1</sup>



Ruvidar™ localizes  
preferentially inside  
bladder cancer cells <sup>2,3</sup>



Green laser light  
activates Ruvidar™  
through fiber optics



Bladder cancer cells  
destroyed by the  
production of singlet  
oxygen and / or Reactive  
Oxygen Species ("ROS")<sup>2</sup>

1) Phase Ib NMIBC clinical study patient cystoscopy photograph, after instillation of Study Drug, prior to TLC-3200 Light Activation, showing TLD-1433 localization to bladder cancer tumours

2) Kalinina S, Breymayer J, Reeß K, Lilge L, Mandel A, Rück A. Correlation of intracellular oxygen and cell metabolism by simultaneous PLIM of phosphorescent TLD1433 and FLIM of NAD(P)H. J Biophotonics. 2018 Oct;11(10):e201800085. doi:10.1002/jbio.201800085. Epub 2018 Jul 9. PubMed PMID: 29877627.

3) Seymour GJ, Walsh MD, Lavin MF, Stratton G, Gardiner RA. Transferrin receptor expression by human bladder transitional cell carcinomas. Urol Res. 1987;15(6):341-4

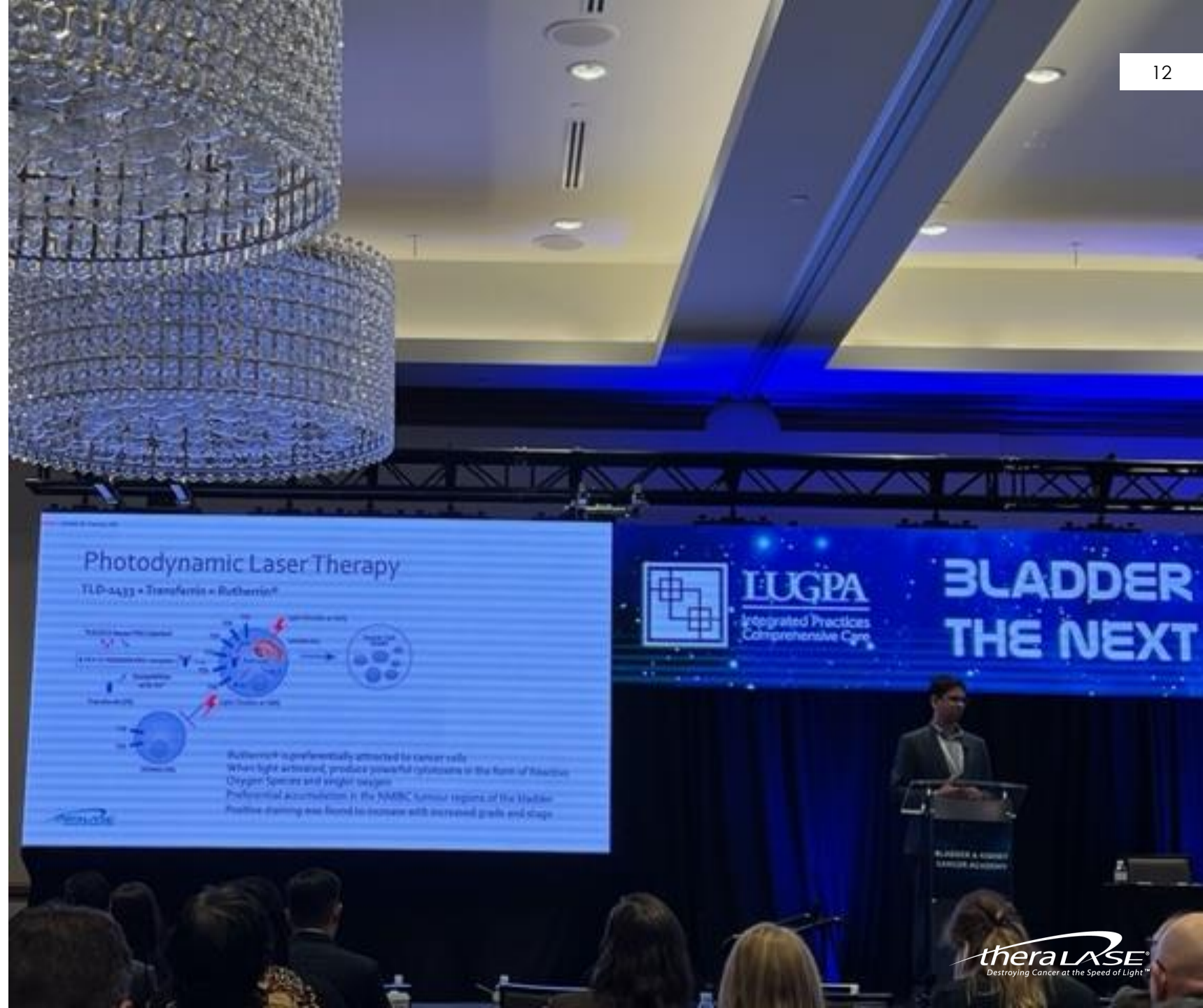
# Clinical Target

A clinically meaningful initial Complete Response Rate (“CRR”) for Carcinoma In-Situ (“CIS”) or recurrence-free rate (for papillary tumors) of at least:

- 50% at 6 months
- 30% at 12 months
- 25% at 18 months

is recommended. (International Bladder Cancer Group (“IBCG”))<sup>1</sup>

1) Kamat AM et al. J Clin Oncol. 2016; 34: 1935-1944





# Phase II NMIBC Clinical Study<sup>1</sup>

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## Study design consistent with FDA Guidance:

“In BCG-Unresponsive NMIBC, a single-arm clinical trial with Complete Response Rate (“CRR”) and duration of response as the primary endpoint can provide primary evidence of effectiveness to support a marketing application”<sup>2</sup>

### Primary Objective

#### Initial Efficacy (CR achieved at any point in time)

- 1) Negative cystoscopy and negative cytology
- 2) Positive cystoscopy (low grade disease) and negative cytology)
- 3) Negative cystoscopy and positive cytology (if random bladder biopsies are negative)

### Secondary Objective

#### Duration of Efficacy (12 months duration of CR after diagnosis of initial CR)

15 months from primary Study Procedure

Patient followed for up to 36 months to demonstrate duration of response

### Tertiary Objective

#### Safety

Incidence and severity of Adverse Events (“AEs”) > Grade 3, directly related to the Study Drug or Study Device, that do not resolve within 450 days post primary study procedure

**Grade 1** = Mild

**Grade 2** = Moderate

**Grade 3** = Severe

**Grade 4** = Life-threatening

**Grade 5** = Death

1) Clinical Protocol TLD-1433-2 (Version 12.0). December 6, 2023

2) “BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment – Guidance for Industry”. February 2018. [www.fda.gov/media/101468/download](http://www.fda.gov/media/101468/download)



# Study Procedure

- Approximately 75 to 100 patients with BCG-Unresponsive NMIBC CIS
- 10 clinical study sites currently enrolling patients in Canada and the United States (Up to 15 in 2024)
- Patient provided primary Study Procedure on Day 0 (1 hour of drug instillation, 1 hour of light activation)
- Outpatient procedure
- Surgeon has the option to deliver up to 2 more re-induction Study Procedures, if the patient recurs
- Patient followed up quarterly for 2 years and then semi-annually for 1 additional year (3 years in total)



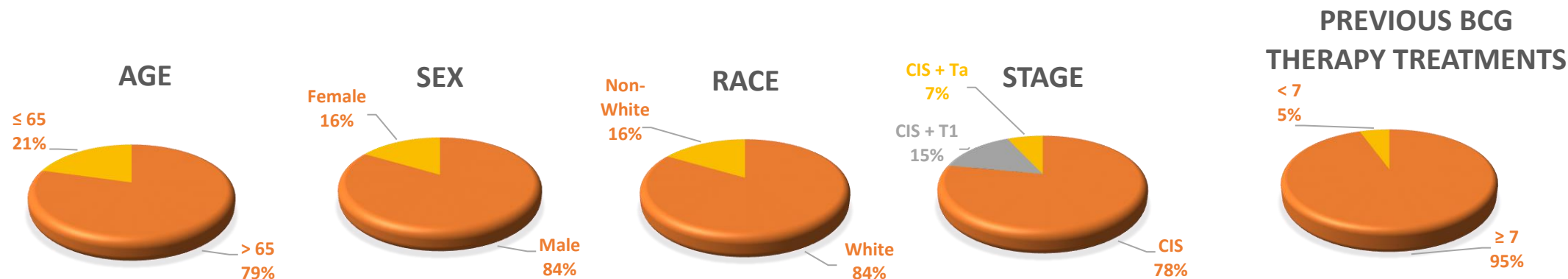
THE UNIVERSITY  
OF BRITISH COLUMBIA



# Phase II NMIBC Interim Clinical Data<sup>1</sup>

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## Patient Demographics



Ruvidar™ has been demonstrated to achieve complete responses in patients, previously treated with and who failed therapy with: BCG, systemic PD-L1 immunotherapies and chemotherapies, intravesical oncolytic viruses and intravesical chemotherapies (gemcitabine with or without docetaxel).

# Phase II NMIBC Interim Clinical Data<sup>1</sup>

	Primary Objective Performance			Secondary Objective Performance			Tertiary Objective Performance		
	#	%	Confidence Interval (95%)	#	%	Confidence Interval (95%)	#	%	Confidence Interval (95%)
Complete Response ("CR")	41	60.3%	18.5%	18	26.5%	12.23%	68	100.0%	
Indeterminate Response ("IR")	8	11.8%	8.2%	1	1.5%	2.88%	0	0.0%	
Total Response (CR and IR)	49	72.1%	20.2%	19	27.9%	12.56%	68	100.0%	
Evaluable Patients	68			23			68		
Pending	7			13			7		
Total Patients	75			36			75		

**According to the Kaplan-Meier Curve, if CR is obtained, then the patient is estimated to have a 47.8%, 42.6% and 35.6% chance of remaining cancer free for 1, 2, and 3 years, respectively.**

**Note:** The data analysis is only a representation of the data accrued to date and does not intend to represent a tendency or portray any conclusion as to the effectiveness, duration or safety of the investigational treatment.

**Note:** Indeterminate Response ("IR") is defined as negative cystoscopy (no evidence of Urothelial Cell Carcinoma ("UCC") in the bladder) and positive / suspicious urine cytology (detection of cancer in the urine, without a negative confirmatory bladder biopsy, suggesting UCC in the renal system other than the bladder)

# Phase II NMIBC Interim Clinical Data<sup>1</sup>

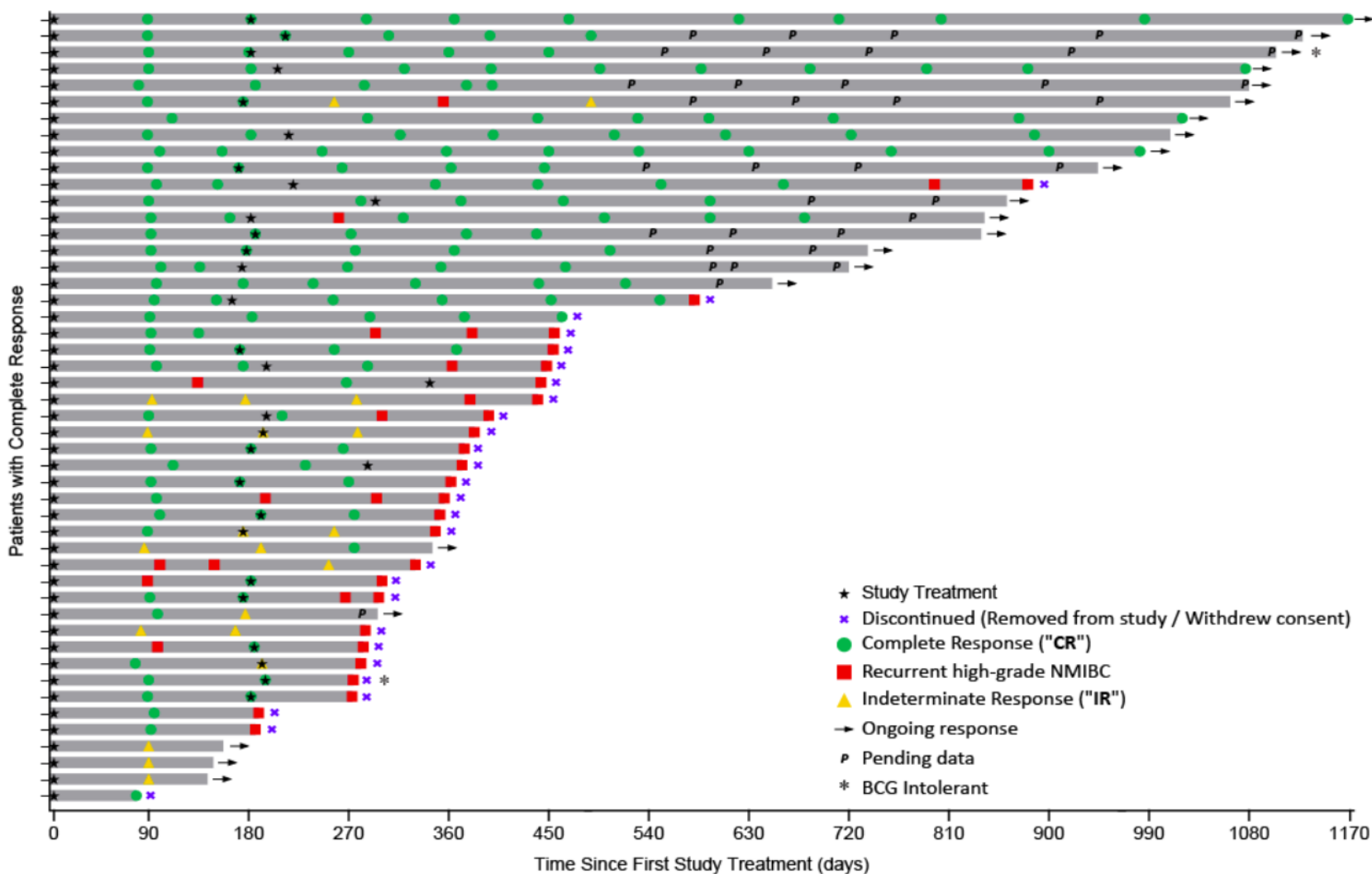
In response to the FDA request, there is a demonstrated duration of CR of 13.2% (9/68) at 540 days, 8.8% (6/68) at 630 days, 7.4% (5/68) at 720 days, 7.4% (5/68) at 900 days and 5.9% (4/68) at 1080 days, with significant clinical data still pending.

	90 Days		180 Days		270 Days		360 Days		450 Days		540 Days		630 Days		720 Days		900 Days		1080 Days	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Complete Response ("CR") (Negative Cystoscopy and Negative Urine Cytology)	33	48.5%	30	44.1%	18	26.5%	13	19.1%	14	20.6%	7	10.3%	5	7.4%	4	5.9%	4	5.9%	3	4.4%
Complete Response ("CR") (Positive Cystoscopy (Low Grade) and Negative Urine Cytology)	1	1.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Complete Response ("CR") (Negative Cystoscopy and Suspicious / Positive Urine Cytology with confirmed upper tract / prostatic urethra disease and negative bladder biopsies)	3	4.4%	3	4.4%	4	5.9%	6	8.8%	4	5.9%	2	2.9%	1	1.5%	1	1.5%	1	1.5%	1	1.5%
Complete Response (Total)	37	54.4%	33	48.5%	22	32.4%	19	27.9%	18	26.5%	9	13.2%	6	8.8%	5	7.4%	5	7.4%	4	5.9%
Indeterminate Response ("IR")	6	8.8%	7	13.0%	5	7.4%	0	0.0%	1	1.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Response (CR and IR)	43	63.2%	40	61.5%	27	39.7%	19	27.9%	19	27.9%	9	13.2%	6	8.8%	5	7.4%	5	7.4%	4	5.9%
Evaluable Patients	68		54		46		34		23		10		8		6		5		4	
Pending	7		11		12		13		13		20		21		21		21		22	
Total Patients	75		65		58		47		36		30		29		27		26		26	

Analyzing Total Response (CR + IR) 72.1% (49/68) [95% CI: 51.9%, 92.3%] of patients achieved complete destruction of their bladder cancer at any point in time and 27.9% (19/68) [95% CI: 15.3%, 40.5%] had a duration of this response for at least 450 days, with significant clinical data still pending.

# Phase II NMIBC Interim Clinical Data<sup>1</sup>

The Swimmer's plot below is a graphical representation of the interim clinical results (n=41) for patients who achieved a CR at any point in time and their response over 1080 days, graphically demonstrating a patient's response to a treatment over time. As can be seen in the plot, clinical data is still pending for patients, who have demonstrated an initial CR at 90 days and continue to demonstrate a duration of that response.



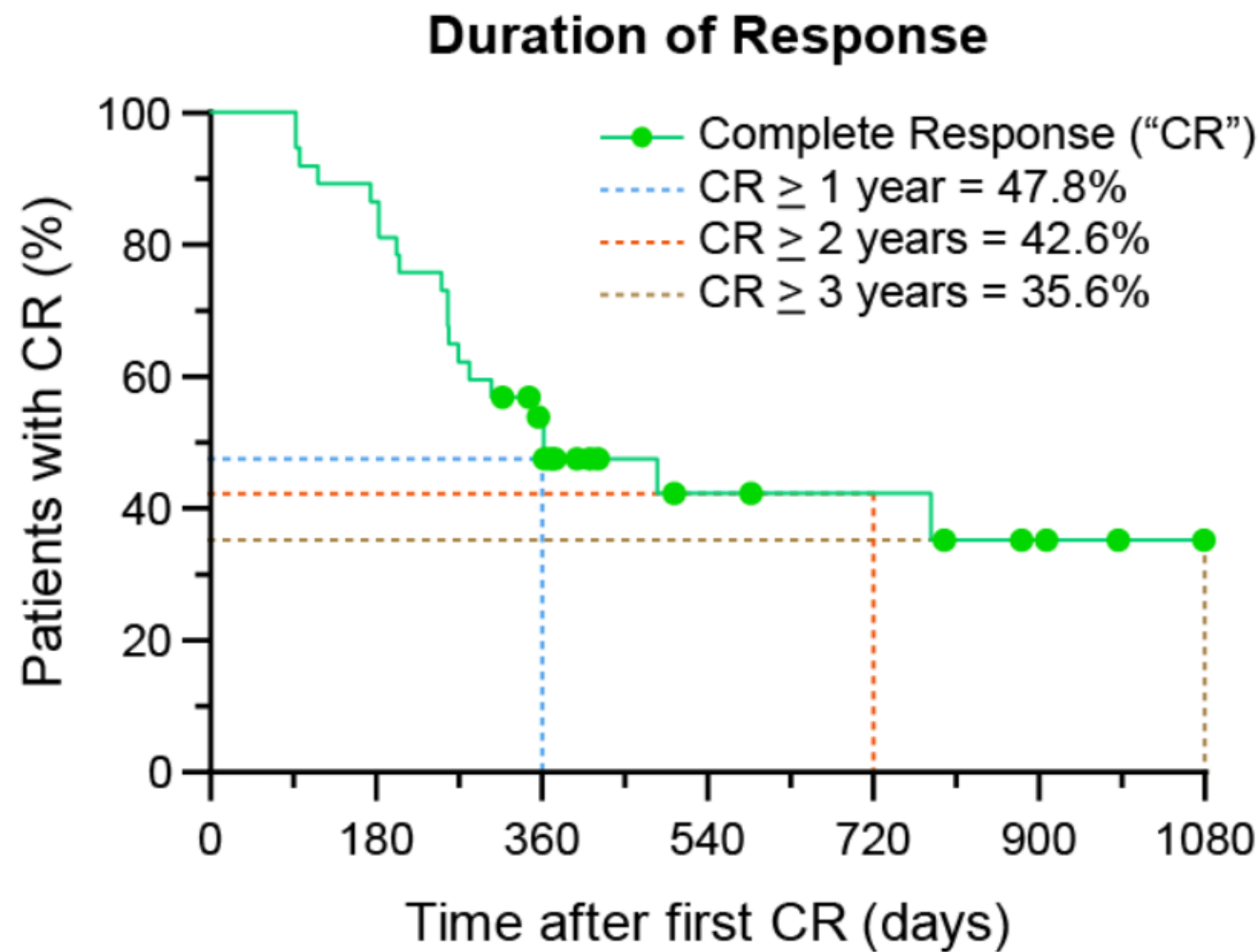
1) Press Release - Theralase® Releases 2Q2024 Financial Statements – October 7, 2024



# Phase II NMIBC Interim Clinical Data<sup>1</sup>

In summary, the interim clinical data demonstrates that patients consenting to participate in Study II have a 60.3% chance of achieving CR.

If CR is obtained, then the patient is estimated to have a 47.8%, 42.6% and 35.6% chance of remaining cancer free for 1, 2, and 3 years, respectively.



1) Press Release - Theralase® Releases 2Q2024 Financial Statements – October 7, 2024

## **Serious Adverse Events**

For 75 patients treated in Study II, there have been 15 Serious Adverse Events (“SAEs”) reported:

- 1 – Grade 1 (resolved in 9 days)
- 3 – Grade 2 (resolved within 1, 1 and 33 days, respectively)
- 7 – Grade 3 (resolved within 1, 2, 3, 4, 4, 82 and unknown days, respectively)
- 3 – Grade 4 (resolved within 3, 6 and 8 days, respectively)
- 1 – Grade 5

Theralase® believes all SAEs reported to date are unrelated to the Study Drug or Study Device.

**Note:** A SAE is defined as any untoward medical occurrence that at any dose: Is serious or life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect or results in death.

# FDA Approved Drugs

Company/ FDA Approved Drug (Date of Approval)	Number of Patients	Initial Complete Response ("CR")	Duration of Response (12 months) (24 months) (36 months)			Pros	Cons	Annual Cost (\$USD 000s)	Market Capitalization (\$USD Billion)
Endo Pharmaceuticals Valrubicin (Valstar) <sup>1, 2</sup> (1981)	90	21%	7.7%	4.0%	Not Reported	First intravesical drug approved by the FDA for NMIBC.	Not a BCG-Unresponsive population. Not recommended by US uro-oncologists	\$55 (Once a week for 6 weeks)	\$0.00014
Merck Pembrolizumab (Keytruda*) <sup>3, 4</sup> (2020)	96	40.6%	18.8%	9.4%	0%	First immunotherapy drug approved for BCG- Unresponsive NMIBC CIS.	Patients must have PD-L1 expression to generate a response. Only applicable to 20 to 40% of patient population. Associated with serious adverse events, not recommended.	\$150 (Every 3 weeks for up to 24 months)	\$319
Ferring Adstiladrin <sup>5</sup> (2023)	98	51.0%	23.5%	19.4%	13.6%	First intravesical oncologic virus approved for BCG- Unresponsive NMIBC CIS.	Median Duration Of Response ("DOR") of 9.7 months.	\$211 (Once every 3 months) (\$60 per installation)	\$2.2 (Annual Revenue)
Immunity Bio BCG + N803 <sup>6</sup> (Intravesical SL-15 agonist) (Estimated for 2026)	77	62.3%	36.4%	24.7%	Not Reported	High initial efficacy and duration of efficacy.	Combinational product, combined with standard of care TICE BCG, which is in shortage in the US. BCG contributes efficacy in the patient population.	\$215 (Once a week for 6 weeks) (\$35.8 per dose + BCG)	\$3.1

1) Steinberg G, Bahnson R, Brosman S, Middleton R, Wajzman Z, Wehle M. Efficacy and safety of valrubicin for the treatment of Bacillus Calmette-Guerin refractory carcinoma in situ of the bladder. The Valrubicin Study Group. J Urol. 2000 Mar;163(3):761-7. Erratum in: J Urol. 2008 Jan;179(1):386. PMID: 10687972.

2) Dinney CPN et al. Intravesical valrubicin in patients with bladder carcinoma in situ and contraindication to or failure after bacillus Calmette-Guérin. Urol Oncol. 2013 Nov;31(8):1635-42

3) Balar, A.V., et al., Pembrolizumab monotherapy for the treatment of high-risk non-muscle-invasive bladder cancer unresponsive to BCG (KEYNOTE-057): an open-label, single-arm, multicentre, phase 2 study. Lancet Oncol, 2021. 22(7): p. 919-930.

4) Press Release – Merck's KEYTRUDA® (pembrolizumab) Showed a Complete Response Rate of Nearly 40 Percent in Patients with High-Risk Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Standard of Care – October 20, 2018

5) FDA Press Announcement. FDA Approves First Gene Therapy for the Treatment of High-Risk, Non-Muscle-Invasive Bladder Cancer.

6) Press Release – ImmunityBio Announces FDA Approval of ANKTIVA®, First-in-Class IL-15 Receptor Agonist for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer – April 22, 2024

\*KEYTRUDA® is a registered trademark of Merck & Co. Inc.

# Competitive (Non-FDA Approved) Drugs Versus Ruvidar™

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Competitive Drug (Non-FDA Approved)	Number of Patients	Initial Complete Response ("CR")	(12 months)	Duration of Response (24 months)	(36 months)	Pros	Cons	Annual Cost (\$USD 000s)	Market Capitalization (\$USD Billion)
Johnson and Johnson Slow-Release Gemcitabine <sup>1</sup> (Intravesical chemotherapy) (Estimated for 2026)	85	83.5%	20.7%	Not Reported	4.7%	High initial efficacy	Gemcitabine may result in little to no difference in the risk of disease progression compared to saline. Serious adverse events associated with chemotherapy. Median Duration Of Response ("DOR") of 30 weeks	\$Unknown (Dosed every 3 weeks for 24 weeks, followed by every 12 weeks through week 96)	\$372.3
CG Oncology Cretostimogene grenadenorepvec <sup>2</sup> (Intravesical oncolytic immunotherapy) (Estimated for 2026)	105	75.2%	29.5%	Not Reported	Not Reported	High initial efficacy	Biological drugs are prone to manufacturing issues. Gene therapy is not readily adopted by all uro-oncologists due to complexities	\$Unknown (6 weekly treatments, then 6 weekly treatments or 3 weekly treatments based on response, then 3 weekly treatments every 3 months for first 12 months, every 6 months for next 24 months)	\$2.2
Theralase® Ruvidar™ <sup>4</sup> (Estimated for 2026)	75	60.3% CR (72.1% TR) (Interim)	27.9% (Interim)	7.4% (Interim)	5.9% (Interim)	High initial efficacy. 3/5 of patients achieve CR after only 1 study procedure. Demonstrated 8 years shelf life of Ruvidar™	Requirement of operating room for Study Device activation.	\$Unknown (Single procedure)	\$.05
enGene EG-70 (detalimogene voraplasmid) <sup>3</sup> (Non-viral gene therapy) (Estimated for 2028)	22	71% (Interim)	22.7% (Interim - Estimated)	Not Reported	Not Reported	High initial efficacy	Phase II clinical study just commenced.	\$Unknown Unknown treatment schedule	\$0.3

1) TAR-200 monotherapy shows greater than 80% complete response rate in patients with high-risk non-muscle-invasive bladder cancer. May 3, 2024

2) CG Oncology Website – May 30, 2024

3 Press Release – enGene Reports First Quarter 2024 Financial Results and Recent Corporate Progress – March 11, 2024

4) Press Release - Theralase® Releases 2Q2024 Financial Statements – October 7, 2024

# Regulatory Timeline

Milestone	2019	2020	2021	2022	2023	2024	2025	2026
75 to 100 Patients Enrolled and Provided Primary Study Treatment (Projected)								
FDA Fast Track Designation (Actual)								
Breakthrough Designation (Projected)								
Patient Follow Up (Projected)								
Premarket Approval (Study Device) (Projected)								
Data Lock / Clinical Study Report Submission (Projected)								
Health Canada and FDA Marketing Approval (Projected)								
Commercialization Phase (Projected)								

Regulatory Strategy: Study Drug (IND / NDA) - Study Device (PMA) – Drug / Device Combination



# Capital Structure

TSXV:TLT

10/09/2024

Common share price	\$CAN 0.185	Warrants	37,386,360
Market Capital	\$CAN 45.4 M	Options	8,500,000
Shares Outstanding	242,818,035	Finder Units	18,864
Fully Diluted	288,723,259	Insider Ownership	12.75% Fully Diluted



# Investment Highlights

- Next standard of care treatment for bladder cancer (10<sup>th</sup> most common cancer in the world (6<sup>th</sup> in men))
- Unique value proposition, combining a patented small molecule and proprietary laser system
- Able to directly destroy bladder cancer, leaving healthy bladder cells intact and providing a secondary response through activation of the immune system
- 75 patients enrolled and provided the primary study treatment in an FDA Phase II registration clinical study
- Pending Health Canada and FDA approved, Theralase® will gain access to worldwide cancer markets estimated to be up to \$USD 7 B annually
- Best in class duration of response versus FDA approved drugs and drugs currently under clinical investigation



## Contact Information

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