

#### **Prescient Therapeutics – Investor Briefing**

**MELBOURNE Australia, 31<sup>st</sup> March 2025:** Prescient Therapeutics Limited (ASX: PTX), a clinical stage oncology company developing personalised therapies for cancer, will be holding an investor briefing on Monday, 31<sup>st</sup> March at 12pm (AEDT).

CEO James McDonnell will provide a company update, outlining the next critical phase towards approval and commercialisation of PTX-100.

To register for the investor briefing, visit this page: <a href="https://prescienttherapeutics.investorportal.com.au/investor-briefing/">https://prescienttherapeutics.investorportal.com.au/investor-briefing/</a>

A copy of the investor presentation to be presented is attached.

- Ends -

To stay updated with the latest company news and announcements, <u>please update your details</u> on our investor centre.

#### **About Prescient Therapeutics Limited (Prescient)**

Prescient Therapeutics (ASX: PTX) is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

#### Targeted Therapy

PTX-100: is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase-1 (GGT-1). It disrupts oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to apoptosis (death) of cancer cells. PTX- 100 is believed to be the only GGT-1 inhibitor in the world in clinical development. PTX-100 demonstrated safety and early clinical activity in a previous Phase 1 study and recent PK/PD basket study of hematological and solid malignancies. PTX-100 has recently completed a Phase 1b expansion cohort study in T cell lymphomas, where it showed encouraging efficacy and safety. The US FDA has granted PTX-100 Orphan Drug Designation for all T Cell Lymphomas. A Phase 2 study in Cutaneous T cell lymphoma (CTCL) is planned for initiation in April 2025.

#### **Cell Therapy Platforms**

**CellPryme-M**: Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances cell therapy performance by shifting T cells toward a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours. CellPryme-M is a 24-hour, non-disruptive process during cell manufacturing. Cell therapies that could benefit from additional productivity in manufacturing or increased potency and durability in-vivo, would be good candidates for CellPryme-M.



**CellPryme-A**: CellPryme-A is an adjuvant therapy designed to be administered to patients alongside cellular immunotherapy to help them overcome a suppressive tumour microenvironment. CellPryme-A significantly decreases suppressive regulatory T cells; increases expansion of CAR-T cells in vivo; increases tumour penetration of CAR-T cells. CellPryme-A improves tumour killing and host survival of CAR-T cell therapies, and these benefits are even greater when used in conjunction with CellPryme-M pre-treated CAR-T cells.

**OmniCAR**: is a universal immune receptor platform enabling controllable T-cell activity and multi- antigen targeting with a single cell product. OmniCAR's modular CAR system decouples antigen recognition from the T-cell signalling domain. It is the first universal immune receptor allowing post- translational covalent loading of binders to T-cells. OmniCAR is based on technology licensed from Penn; the SpyTag/SpyCatcher binding system licensed from Oxford University; and other assets. OmniCAR is in pre-clinical development.

The targeting ligand can be administered separately to CAR-T cells, creating on-demand T-cell activity post infusion and enables the CAR-T to be directed to an array of different tumour antigens. OmniCAR provides a method for single-vector, single cell product targeting of multiple antigens simultaneous or sequentially, whilst allowing continual re-arming to generate, regulate and diversify a sustained T-cell response over time.

Find out more at www.ptxtherapeutics.com or connect with us via LinkedIn.

The Board of Prescient Therapeutics Limited has approved the release of this announcement.

#### For more information please contact:

Company enquiries

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CEO

Prescient Therapeutics

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#### **Disclaimer and Safe Harbor Statement**

Certain statements made in this document are forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts but rather are based on the current expectations of Prescient Therapeutics Limited ("Prescient" or the "Company"), their estimates, assumptions, and projections about the industry in which Prescient operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance', and similar expressions are intended to identify forward-looking statements and should be considered an at-risk statement. These forward-looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Prescient or which are difficult to predict, which could cause the actual results, performance, or achievements of Prescient to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, global pandemics and related disruptions, the impact of pharmaceutical industry development and health care legislation in the United States and internationally, and challenges inherent in new product development. In particular, there are substantial risks in drug development including risks that studies fail to achieve an acceptable level of safety and/or efficacy. Investors should be aware that there are no assurances that results will not differ from those projected and Prescient cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Prescient only as of the date of this announcement. Prescient is not under a duty to update any forwardlooking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

Certain statements contained in this document, including, without limitation, statements containing the words "believes," "plans," "expects," "anticipates," and words of similar import, constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of Prescient to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the risk that our clinical trials will be delayed and not completed on a timely basis; the risk that the results from the clinical trials are not as favourable as we anticipate; the risk that our clinical trials will be more costly than anticipated; and the risk that applicable regulatory authorities may ask for additional data, information or studies to be completed or provided prior to their approval of our products. Given these uncertainties, undue reliance should not be placed on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future events or developments except as required by law.

This document may not contain all the details and information necessary for you to make a decision or evaluation. Neither this document nor any of its contents may be used for any other purpose without the prior written consent of the Company.

#### **Supplemental COVID-19 Risk Factors**

Please see our website: Supplemental COVID-19 Risk Factors



# MAJOR

# NFLEGTON

### **DISCLAIMER AND SAFE HARBOR**



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# 3 Key Messages





#### A major inflection point with Phase 2 Initiation

- Phase 2a clinical trial has begun
- Encouraging data in an area of unmet need
- First in class with a wider application



#### Lower risk exposure to cell therapy sector

- Improves 3<sup>rd</sup> party cell therapies
- Agnostic on cell type and targets

\$12.1 Million\*

Well capitalised to deliver on milestones

\*Near-term Liquidity (Jan 2025): \$12.1m

- Cash (31 Dec): \$6.4m
  - Deposits (matured 9 Jan): \$2.0m
- R&D Rebate (received 10 Jan): \$3.7m

# PTX: Targeting Improved Oncology Patient Outcomes

Through novel approaches to treat cancer including targeted and cell therapies Led by an experienced team of drug developers and deal makers with a track record in blood cancers

#### PTX-100

- Targeted therapy one of the most advanced cancer therapies on ASX
- Treats cancers with high mortality rates and high unmet need
- Promising Phase 1b results in T Cell Lymphoma (TCL)
  - √ 64% response either halting or reducing disease
  - ✓ Extended duration of response compared to approved alternatives
  - ✓ Safety profile may have advantages in comparison to other treatment options
- Phase 2 study in Cutaneous T Cell Lymphoma (CTCL) underway
- FDA Orphan Drug Designation provides market exclusivity, regulatory support and fast-track approval potential
- Total TCL market US\$1.8B market in 2030 for 8 major markets\*

#### **Pre-clinical assets**

OmniCAR and CellPryme platforms have potential to improve CAR-T therapies

# **Experienced team**



Experienced team of drug developers and deal makers with track record in blood cancers

#### Management Team



James McDonnell



Dr. Marissa Lim Chief Medical Officer



Upaly Bahadure
Director – Clinical Affairs &
Operations



Mariam Mansour, PhD
Director - Clinical
Development and
Translational Sciences



Luis Malaver-Ortega, PhD
Director Research and
Development

#### Board of Directors



Dr James Campbell
Non-Executive Chairman



Dr Allen Ebens
Non-Executive Director



Dr Ellen Feigal
Non- Executive Director



Dr Gavin Shepherd
Non-Executive Director

Experienced gained in global companies





















Genentech

# **Investment Snapshot**



			\
/	ASX Ticker	PTX	)
	Total Issued Capital	805 M shares	
	Share Price <sup>1</sup>	A\$0.048	
	Top 20 Own	18%	
	Market Capitalisation <sup>1</sup>	\$39M	
	Near-term Liquidity <sup>2</sup>	\$12.1M	
	Enterprise Value	\$27M	
			/



- As at 28 March 2025
- 2. Near-term Liquidity (Jan 2025): \$12.1m
  - Cash (31 Dec): \$6.4m
  - Deposits (matured 9 Jan):
     \$2.0m
  - R&D Rebate (received 10 Jan): \$3.7m



**Portfolio Overview** 

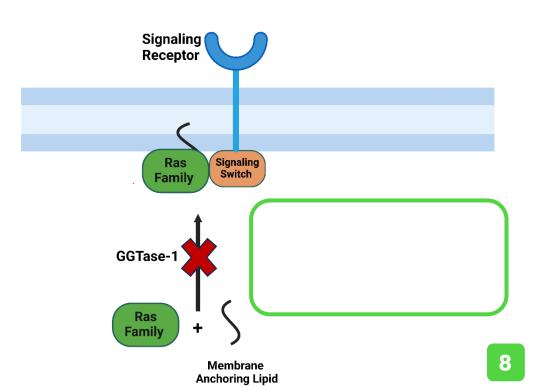
# **PTX-100 First in Class Targeted Therapy**



Inhibition of GGT-1 disrupts small GTPases including:

## the RAS family pathway

- Mutations in RAS are estimated to be responsible for approximately 22% of all human cancers<sup>1</sup>
- PTX-100 targets and blocks an enzyme called GGTase-1, disrupting the RAS family pathways
- This interferes with the way cancer cells grow and spread

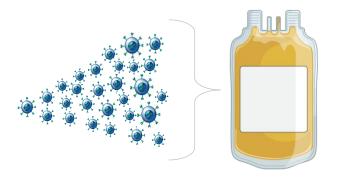


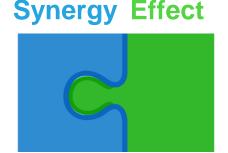
# CellPryme: enhancing cell therapies in two ways













Seamless addition during manufacturing Enhanced CAR-T phenotype

**Enhanced Effectiveness** 

Safely administrated to patient **Enhanced CAR-T therapy** 

# OmniCAR: modular "plug & play" cells

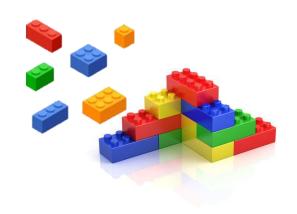


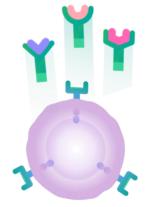
# Traditional CAR-T products

"Plug & play" offers:









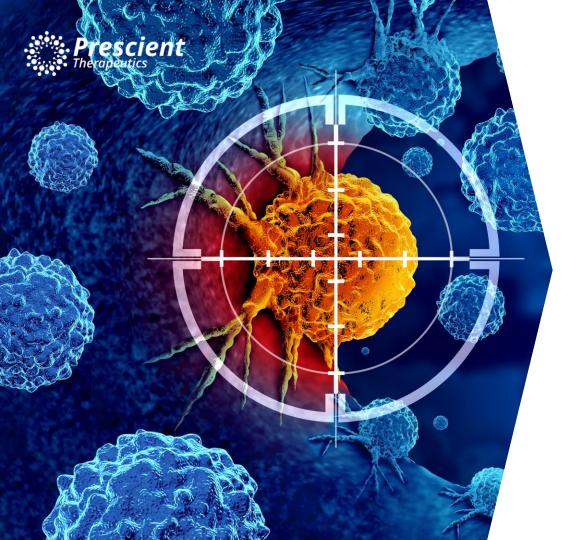




- Permanent target
- Single target
- Fixed

- Increased flexibility
- Multiantigen target
- Better control over cell function
- Modular/Adaptable
- Multi-target
- Tuneable





# PTX-100 1ST IN CLASS TARGETED THERAPY





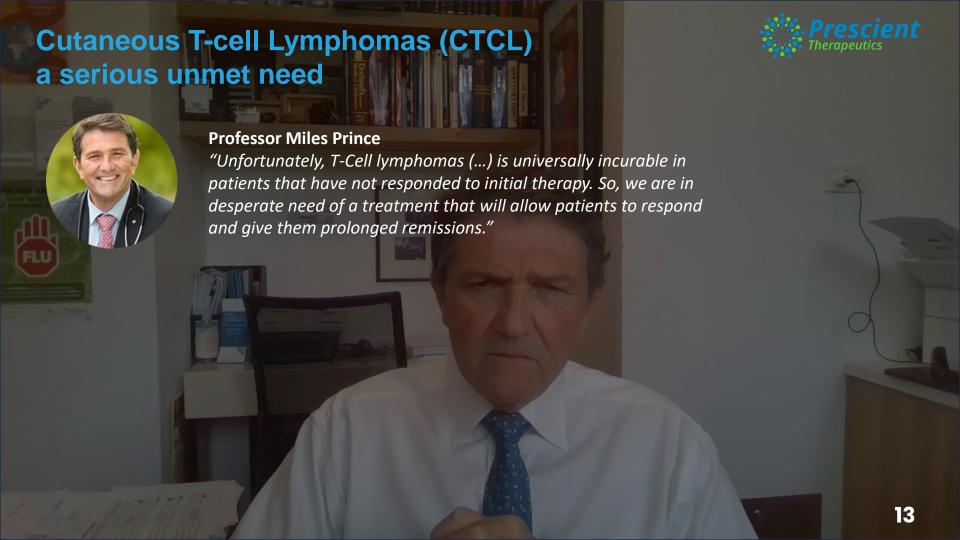
# **Cutaneous T-cell Lymphoma (CTCL) Overview**



- A rare type of cancer of white blood cells (T cells), normally involved in immune function
- These cancerous T cells travel to and live in the skin, where they
  grow and divide uncontrollably, attacking the skin
- CTCLs include subtypes, most commonly Mycosis Fungoides and Sezary Syndrome
- Can be indolent or aggressive, and range from rash-like patches through to plaques and tumours
- Limited options for patients with relapsed or refractory CTCL
- Orphan disease: 3,000# new cases in US each year and increasing
- Market projected to grow to US\$600M in the US by 2032











# **Before**



**After** 







"We are seeing responses in our patients who weren't responding to any other treatments"

Professor H. Miles Prince Principal Investigator

# PTX-100 Phase 1b responses: Strong response rates in evaluable patients



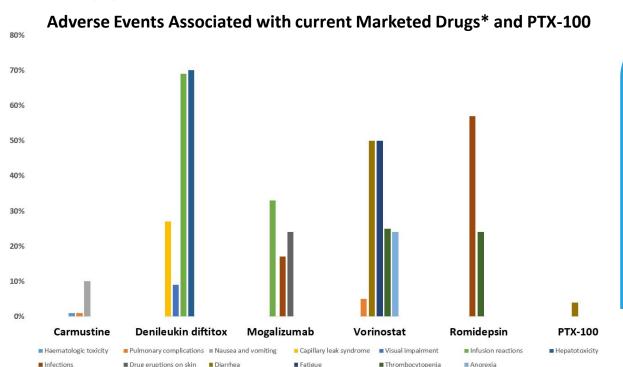
	Benchmark <sup>1</sup>	Lymphir <sup>2,3</sup>	PTX-100 (Phase 1B)
Response Rate			
Clinical Benefit Rate			
Duration of Response			
Serious Adverse Events <sup>4</sup>			

- 1. Considered a target benchmark by Prescient and its investigators, with reference to currently available therapies in r/r TCL
- 2. Label as per FDA.gov; Fierce Pharma; EF Hutton report
- 3. Approved by the FDA 8 Aug 2024
- 4. Assessed as related to drug

## PTX-100: Favorable safety profile compared to peers



Recommended CTCL drugs, as outlined in international cancer treatment guidelines, have challenging safety profiles, with adverse events occurring in up to 70% of patients



# \*Other serious but less common events include Progressive multifocal leukoencephalopathy leading to death, Pancreatitis and Tumour Lysis syndrome. **Brentuximab vedotin** can cause rare but fatal progressive multifocal leukoencephalopathy, and more often pneumonitis, pancreatitis, opportunistic infections, infusion reactions and tumor lysis syndrome.

#### PTX-100 HAS A FAVOURABLE SAFETY PROFILE

- Minimal Serious Adverse Events related to PTX-100
- Suits fragile patient population
- Good candidate for combination therapy

# Rationale of prioritising r/r CTCL for Ph2 trial



#### CTCL

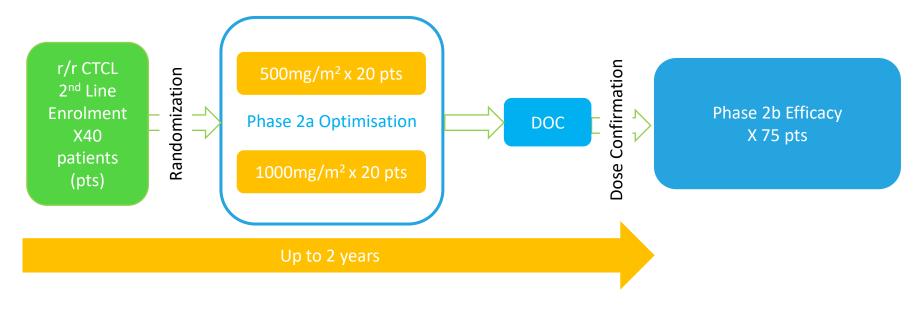
- Higher confidence of PTX-100 in CTCL (more data; more responders)
- Greater need for new therapies
- Likely to recruit faster than PTCL because of lack of trial competition
- Larger patient pool because of high prevalence/longer patient life expectancy
- Likely smaller, faster, cheaper trial design

#### **PTCL**

- Peripheral T Cell Lymphoma (PTCL) is more prevalent than CTCL, but even though PTCL is still an unmet need, it has more existing and emerging competition
- PTCL more likely to require larger, more expensive studies that may require a comparator arm
- Further studies will be conducted under investigator led programs

# **Progressing PTX-100 to Phase 2**





#### **Multicenter clinical trial**

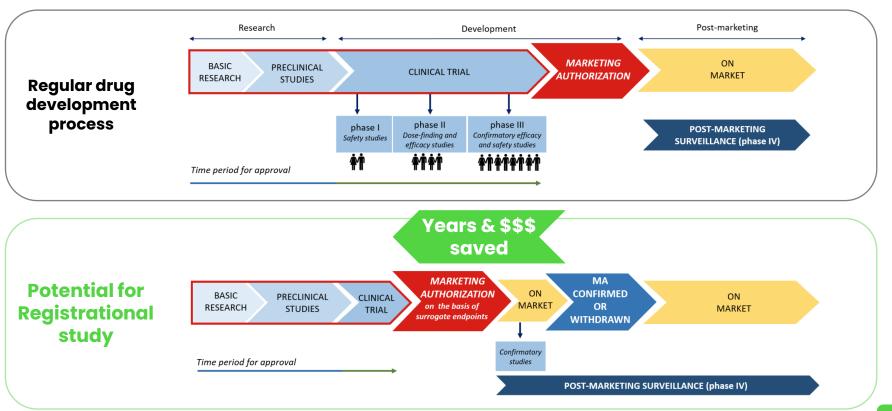
Australia (3) USA (6)

France (3) Italy (3)

- Phase 2a: N=40 pts with r/r CTCL (dose optimization)
- **Phase 2b:** N=75 pts with r/r CTCL will be treated at the recommended dose from Phase 2a
- Involving international experts in CTCL treatment

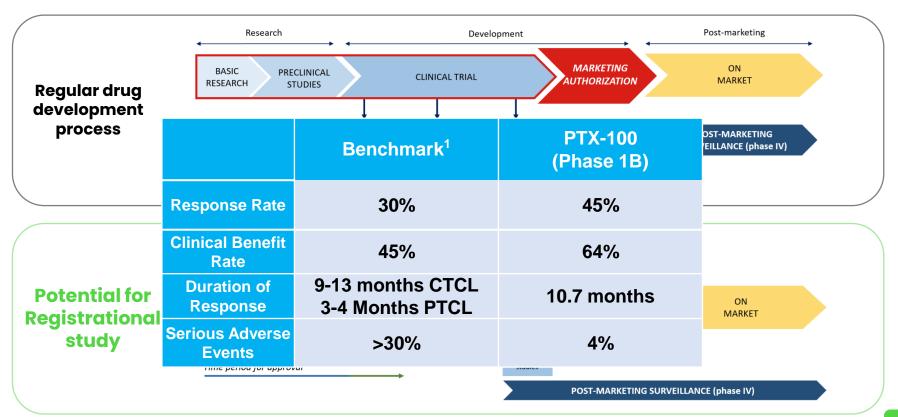
# Aiming for shortened registrational pathway





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# **Advantages of Orphan Drugs**





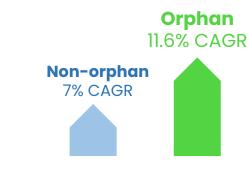
7 years of **guaranteed market exclusivity** in US (10 years in Europe)



**Higher prices** 



Sales are **more resilient** to cycles



Consistently higher sales growth than non-orphan drugs



Total orphan sales to reach **\$US300B** by 2028

# T-cell lymphomas (TCL):



# **High unmet need = Large market opportunity**

#### **Total Addressable Market (TAM)**

- 27,263 new cases / year in the 8 major markets
- Almost all will relapse
- Potential of \$1.8B / year by 2030 (67% in the US)

#### **CTCL US alone**

- Incidence 3,000 patients /annum#
- Almost all will relapse
- Combination therapy likely development
- Potential of \$600M / year in 2032

GlobalData 8 major markets: US, France, Germany, Italy, Spain, UK, Japan, and China

<sup>#</sup> JAMA Oncology.2022 Sep1;8(11):1690–1692.doi:10.1001/jamaoncol.2022.3236

<sup>\*</sup> Estimated cost per patient from Lymphir example

# **Key Milestones in the near future: Implementation will drive value**



Key Milestones	Expected Timing (CY)
First patient in and dosed with PTX-100 (FPID)	April/May
Potential FDA Fast Track designation	Q2
First US site activated and recruiting	Q2/3
First European site activated and recruiting	Q2/3
Continuous review of data during the Phase 2a	Q4 +
Validation of the new OmniCAR receptor and targets for AML	End Q4
Potential channel partner for CellPryme-M	Discussions ongoing

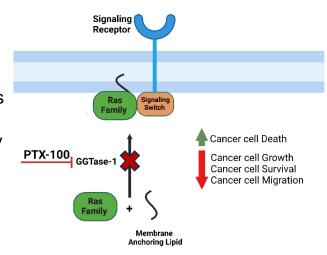




- First in class enzyme inhibitor disrupting the RAS super family pathway, in particular, RHO, RAC and RAL
- 22% of all cancers have RAS involvement

#### **Examples:**

- The RAS super family of genes consists of RAL, RAC, RHO-A/B, plus N-RAS and K-RAS. There are up to 153 proteins. Some examples of cancer types involving mutations of members of the RAS super family are listed below:
  - RAL mutations: Lung, bladder, prostate, hepatocellular, ovarian, pancreatic cancers
  - RHO-A mutations: Burkitt's lymphoma, gastric and breast cancers, PTCL
  - RAC mutations: Breast and prostate cancer, germ cell tumours including testicular cancer



# Summing up PTX-100: Driving a major inflection point



#### **Results:**

#### Phase 1b

- 64% Clinical Benefit
- 10.7 months Duration of Response
- 4% ≥ Grade 3 SAE
- Confidence to move to Phase 2a

#### Timelines:

- Phase 2a is starting now
- Multiple sites globally
- International experts involved
- Recruitment will drive timing

#### Regulatory Pathway/milestones:

- Orphan Designation
- IND acceptance
- Potential Fast Track designation
- TCL aligns with FDA interest in sponsors developing treatments for unmet medical needs
- Registrational potential

#### Market Size:

- TCL market estimated US\$1.8B in 8 major markets in 2030
- CTCL market in US alone estimated at US\$600M in 2032

# 3 Key Messages





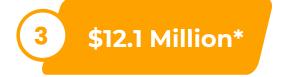
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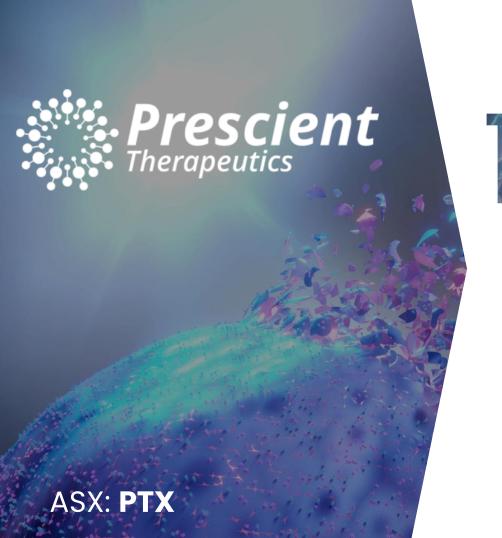


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4C Jan 2025 for December 2024 quarter



# 

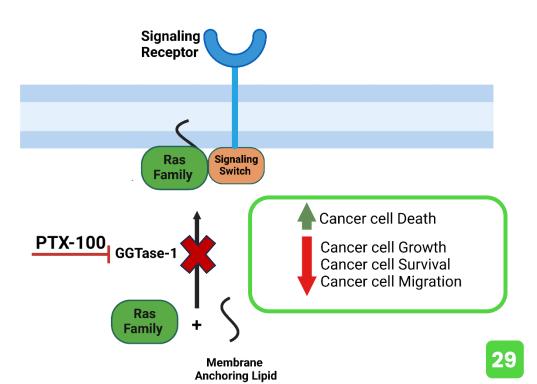
# First in Class Targeted Therapy



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- This interferes with the way cancer cells grow and spread



<sup>1.</sup> The RAS Problem: Turning Off a Broken Switch - NCI

# PTX-100 Phase 1b responses: Strong response rates in evaluable patients



	Benchmark <sup>1</sup>	Lymphir <sup>2,3</sup>	PTX-100 (Phase 1B)
Response Rate	30%	36%	45%
Clinical Benefit Rate	45%	NA	64%
Duration of Response	9-13 months CTCL 3-4 Months PTCL	6.5 months (CTCL)	10.7 months
Serious Adverse Events	>30%	36%	4%

<sup>1.</sup> Considered a target benchmark by Prescient and its investigators, with reference to currently available therapies in r/r TCL

<sup>2.</sup> Label as per FDA.gov; Fierce Pharma; EF Hutton report

<sup>3.</sup> Approved by the FDA 8 Aug 2024