
Prescient
Therapeutics
FASTEST
PATH TO
MARKET
ASX: PTX

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3 Key Messages

1 **PTX-100**

On the verge of a major inflection point

- Starting Ph2 potential registration trial in 2024
- Encouraging data in an area of unmet need

2 CellPryme OmniCAR

Lower risk exposure to cell therapy sector

- Improves 3rd party cell therapies
- Agnostic on cell type and targets

3 **~$14.5M cash**

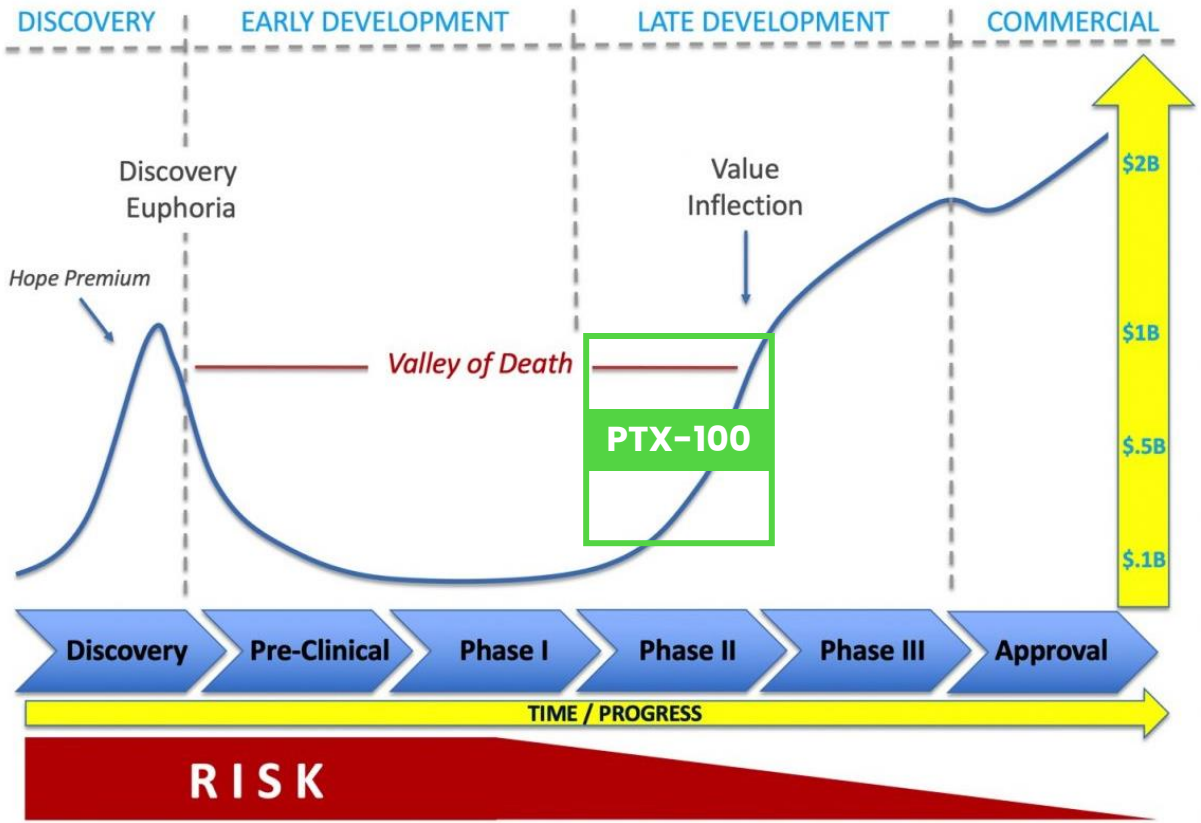
Well capitalised to deliver on milestones

Cash and equivalents as at 30 June 2024

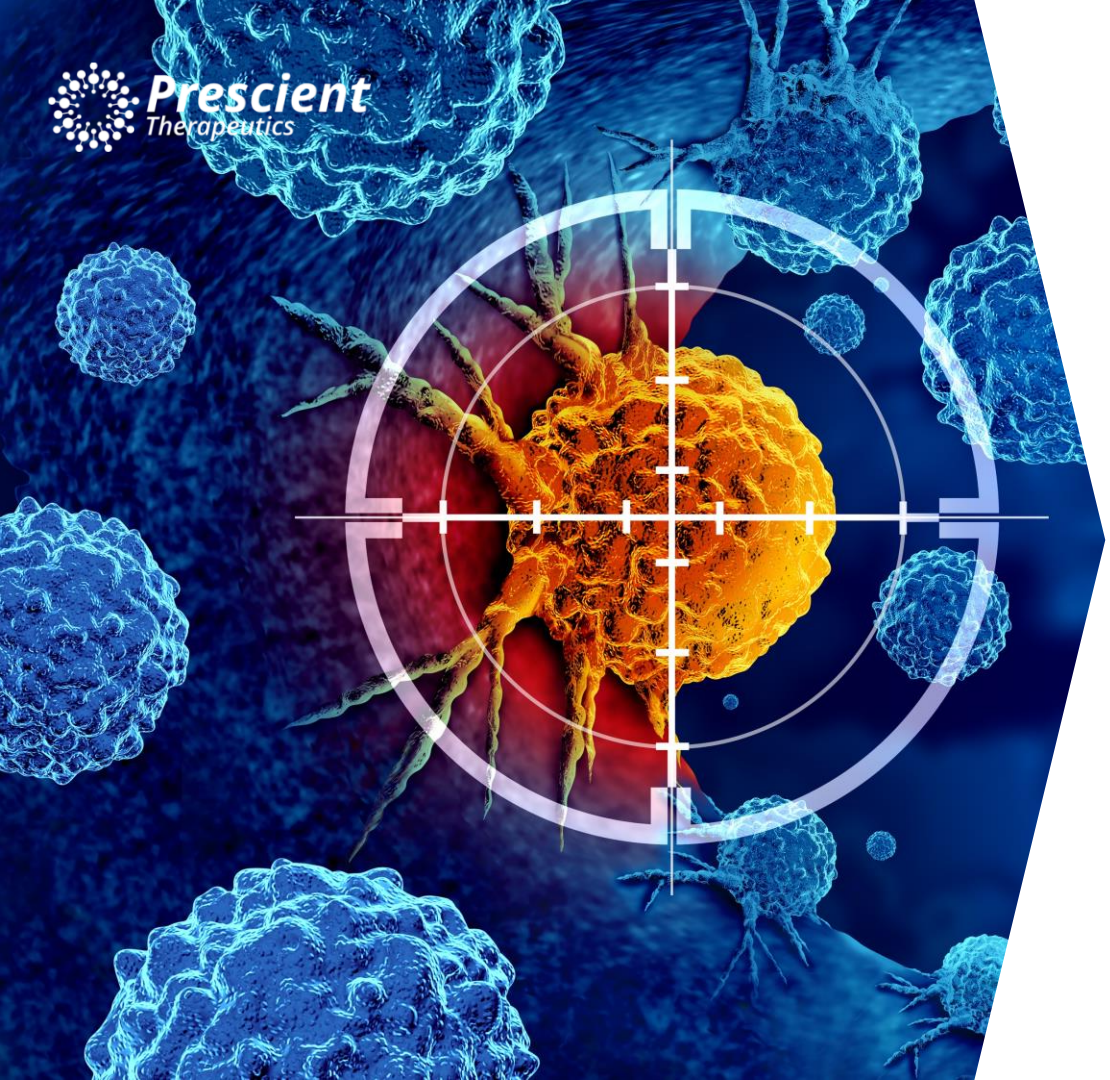
PTX is entering a major inflection point

Prescient Therapeutics

Typical Biotech Value Map



Adapted from Future Healthcare Today , 2021



Prescient Therapeutics

PTX-100

1ST IN CLASS TARGETED THERAPY

Yale University

MOFFITT CANCER CENTER

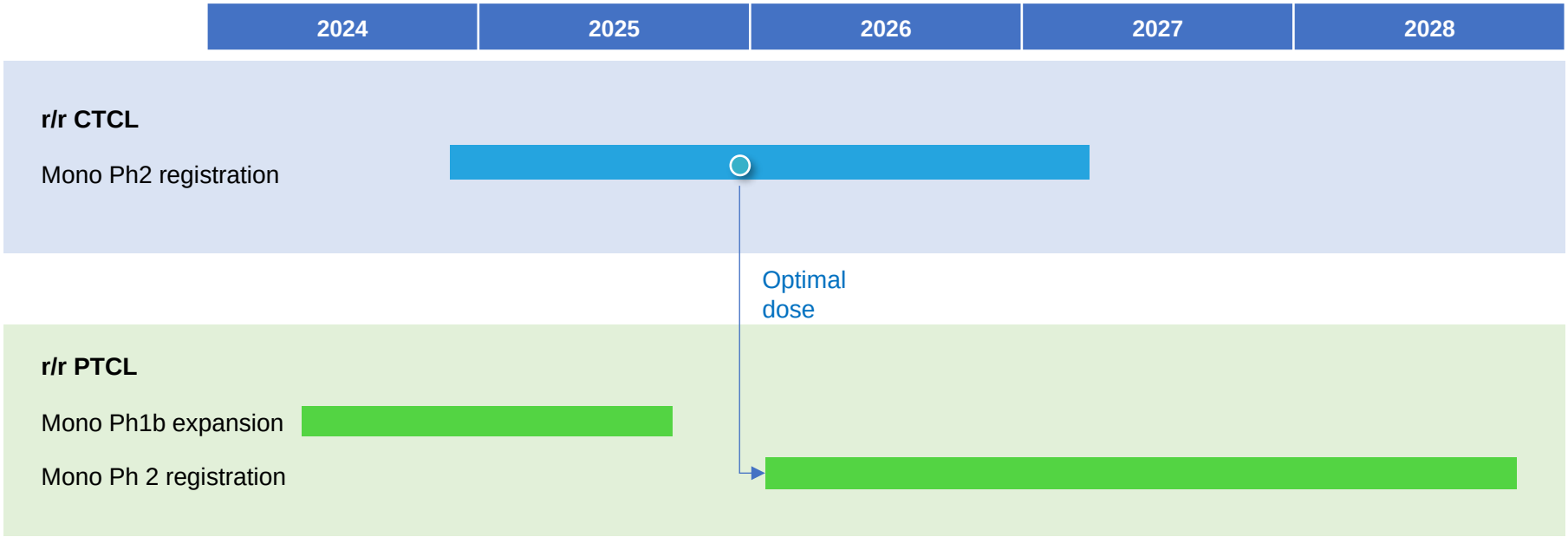
What we've been doing

- Phase 1b trial ongoing, 25 enrolled with one patient still on therapy. Following safety, responses to treatment and duration of responses.
- PK analysis provides insights into dose levels and dosing schedules
- Presenting data and networking at specialist international forums
  - Building awareness with global key opinion leaders and companies
  - Gathering valuable feedback and insights
- Consulting with regulatory experts regarding development strategy and trial design
- Submitted pre-IND questions to US FDA; working with FDA to identify optimal trial design
- Undertaking chemistry, manufacturing & control activities to support the upcoming PTX-100 trial
  - CMC activities required for registration studies are substantially more thorough and stringent than for earlier clinical studies

PTX-100 strategy focussing on speed to market

- Prescient will focus its upcoming Phase 2 trial on **relapsed and refractory CTCL**
  - Faster, smaller trial than broader TCL trial
  - Addresses more urgent medical need with less competition
- Subject to FDA feedback, aiming to commence by end of this year
- Strategy is to **seek approval for CTCL first**, then **leverage this for separate PTCL registration study**
- In meantime, current Ph1b protocol can be expanded to add more PTCL patients
- Optimal dose of PTX-100 determined in CTCL Ph2 trial can be used in PTCL Ph2 trial
- Development plan more efficient and streamlined
- Subsequent opportunities to study beneficial combinations of PTX-100 with existing agents in CTCL and/or PTCL

Potential PTX-100 development plan



NB: Does not take into account the additional opportunities of combining PTX-100 with existing therapies

Rationale of prioritising r/r CTCL for upcoming Ph2 trial

CTCL

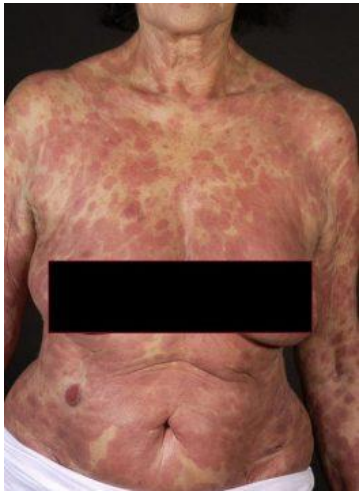
- **Higher confidence** of PTX-100 in CTCL (more data; more responders)
- **Greater need** for new therapies (largely ignored)
- Likely to **recruit faster** than PTCL because of lack of trial competition
- **Larger patient pool** because of high prevalence/longer patient life expectancy
- Likely **smaller,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

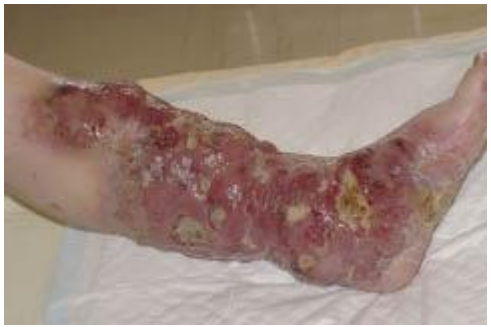
PTCL

- 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
- Use current Ph1b trial to gain more experience with PTCL; upon success, move forward with CTCL optimal dose

What is Cutaneous T-cell Lymphomas (CTCL)?

- 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 group of 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: 1000 new cases in US each year and increasing
- Market projected to grow to US$748M by 2032





Mayo Clinic; Lymphoma Australia; EF Hutton
Images courtesy of *Derm In-Review* and *ADV* Vol 90, Issue 6

Relevant CTCL case study

LYMPHIR™
(denileukin diftitox-cxdl)
Injection 300 mcg

- Fusion protein of IL-2 and diphtheria toxin, developed by Citius and Dr Reddy's
  - Purer version of Eisai's Ontak (withdrawn from market in 2014 due to manufacturing issues)
- Approved in US August 2024 for patients with CD25+ r/rCTCL
- Estimated cost of US$200,000 per patient, per year

Lymphir Registration trial results:

- **ORR: 36%**
- Median duration of response: **6.5 months**
- Safety: adverse events in 98.6% of patients, of which **38% were serious**

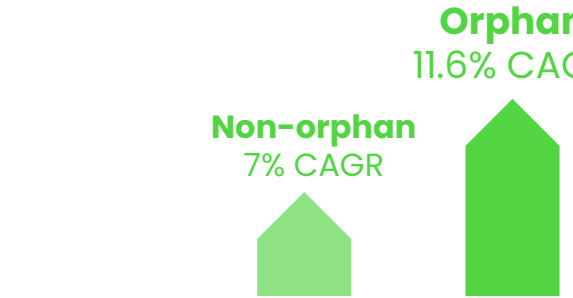
Label as per FDA.gov; Fierce Pharma; EF Hutton report

Advantages of Orphan Drugs

7 years of **guaranteed market exclusivity** in US

Higher prices

Sales are **more resilient** to cycles



Consistently higher sales growth than non-orphan drugs

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

Evaluate Ltd, 2023

PTX-100
Phase 1b study

PTX-100: Ph1b Clinical Summary

- **Aims:** Phase 1b to evaluate safety PK/PD
- **Design:** Dose escalation in advanced malignancies; expansion cohort (n=25) in relapsed & refractory T cell lymphomas
- **Results:**
  - Excellent safety
  - Target engagement at all 3 doses
  - **Response rates (incl 3 CRs) in assessable pts exceeding SoC threshold (30% ORR) to advance program**
- **Granted Orphan Drug Designation by US FDA for all TCLs**

Professor H. Miles Prince, AM
Principal Investigator

Epworth

Drugs for relapsed/refractory TCL can be judged on 3 criteria:

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	Expected
SAFETY	Serious Adverse Events >30% of the time
RESPONSE RATES	~30% patients respond
DURATION OF RESPONSE	For those who respond: CTCL: 9-13 months PTCL: 3-4 months

† Expected DoR 3-4 months for PTCL; 9-13 months for CTCL

PTX-100 is exhibiting an excellent safety profile

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Summary of Treatment-Related Serious Adverse Events (SAEs; Grade ≥ 3)

	PTX-100 500 mg/m² (N=3)	PTX-100 1000 mg/m² (N=3)	PTX-100 2000 mg/m² (N=19)	Overall (N=25)
Subjects with any Treatment Related SAEs	0	0	0	**0**

- **No cases of Serious Adverse Events related to PTX-100**
- Suits fragile patient population
- Good candidate for combination therapy
- Current approved therapies for TCL have significant toxicities* (>30% SAEs)

* Saleh Et. Al. Updates in the Treatment of Peripheral T-Cell Lymphomas; Journal of Exp Pharm 2021:13 577–591

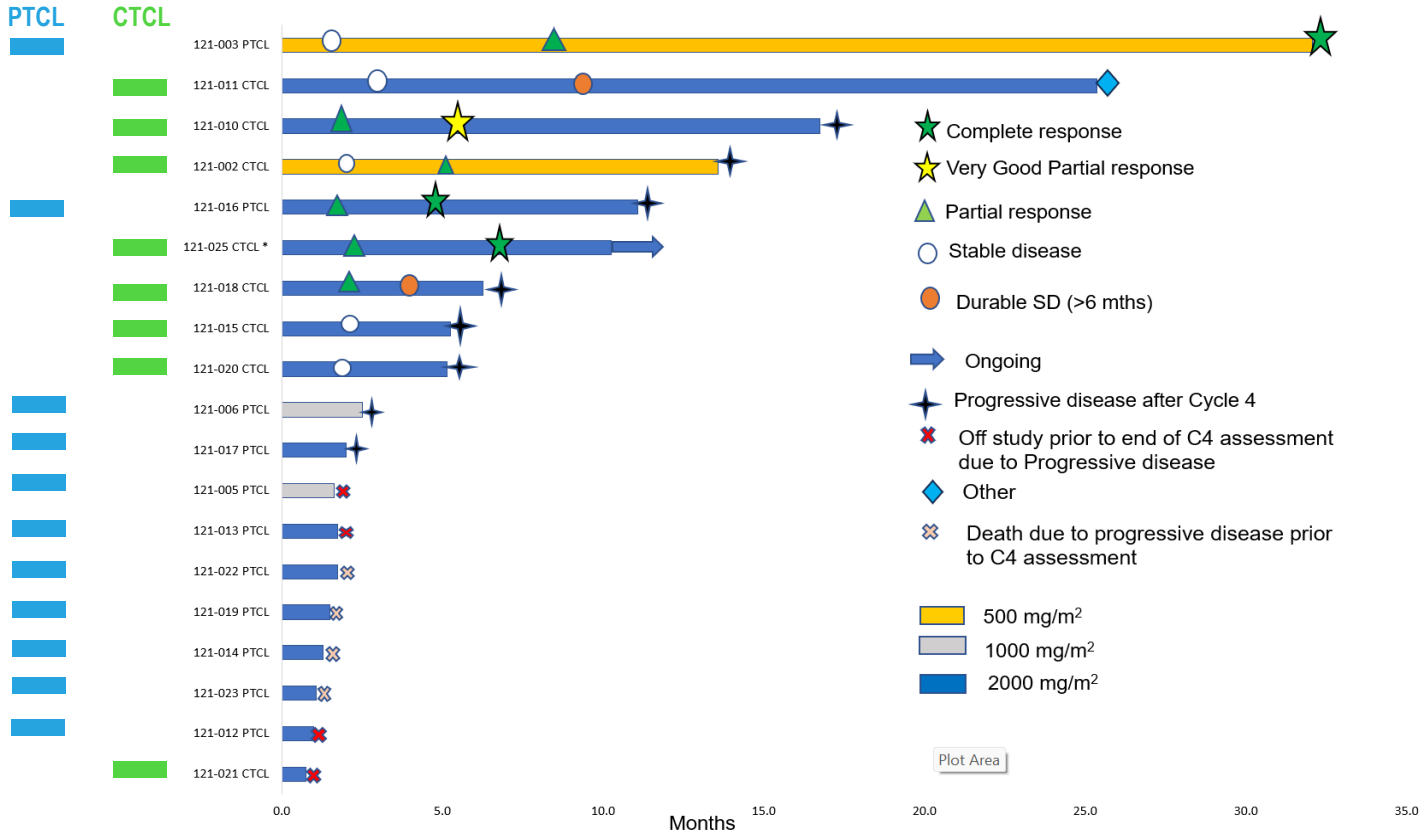
PTX-100 Phase 1b responses:
Strong response rates in evaluable patients

Evaluable for Response (n = 11)	Overall Response Rate CR + PR	Clinical Benefit Rate CR + PR + SD >6 mths
Benchmark[1]	30%	45%
r/r PTCL (n=4)	**50%** (2/4)	**50%** (2/4)
r/r CTCL (n=7)	**43%** (3/7)	**71%** (5/7)
r/r TCL (n=11)	**45%** (5/11)	**64%** (7/11)

Study ongoing; results as at 10 July 2024

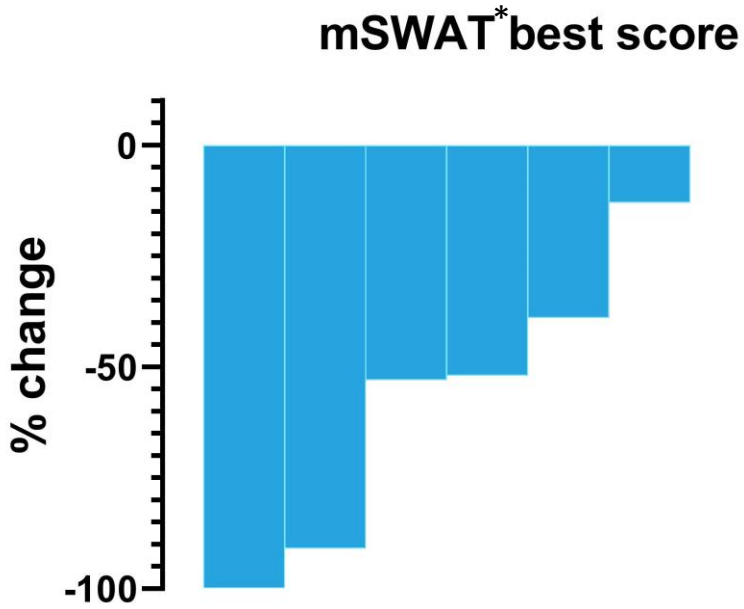
1. Considered a target benchmark by Prescient and its investigators, with reference to currently available therapies in r/r TCL

PTX-100 Phase 1b study swimmer plot



Study ongoing; results as of 3 Sept 2024
*Patient 121-025 (complete response) is still active and on treatment.

Disease reduction in r/r CTCL patients



Significant reduction of mSWAT* score in 6 out 7 r/r CTCL patients

(13-100% reduction)

*mSWAT (Modified Severity-Weighted Assessment Tool) is a measure of disease in CTCL patients

Study ongoing; results as of 3 September 2024, with one patient is still active and on treatment.

PTX-100 Phase 1b Study Summary

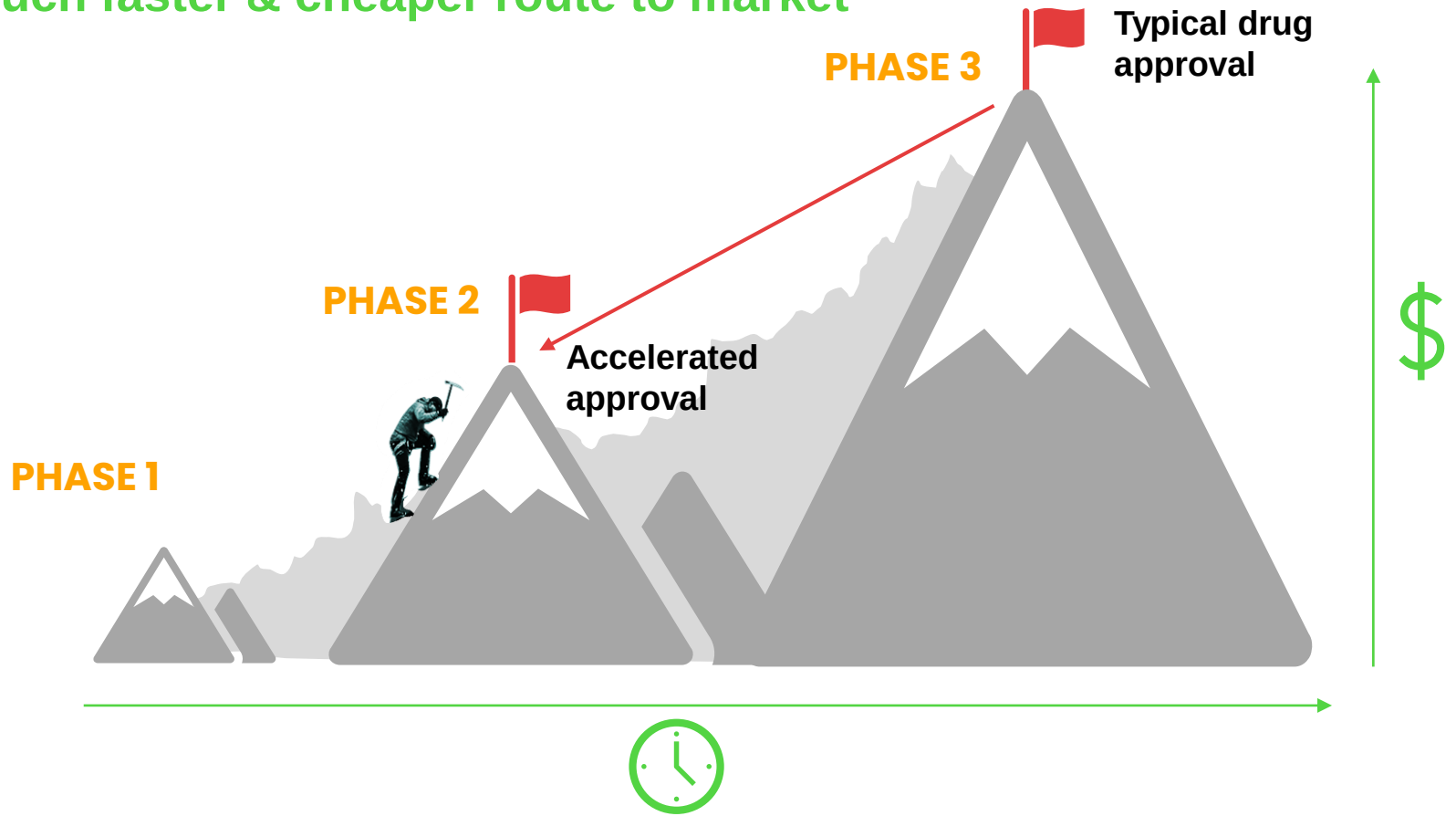
- PTX-100 showed GGT-1 sustained inhibition at all doses.
- PTX-100 showed serum levels that exceeded the IC50 necessary for tumor inhibition.
- PTX-100 was overall well tolerated at 2000 mg/m^2 with no related serious adverse events
- PTX–100 demonstrated clinical activity in patients with relapsed/refractory T cell lymphoma
  - ORR of 45% and sustained clinical benefit in 67% of evaluable patients
  - Durable responses observed in PTCL and CTCL
- Very encouraging data ahead of planned Phase 2 study. Study ongoing; intend to recruit additional PTCL patients.

PTX-100 stacks up favourably against all benchmark TCL criteria:

	Expected	PTX-100
SAFETY	Serious Adverse Events >30% of the time	✓
RESPONSE RATES	~30% patients respond	✓
DURATION OF RESPONSE	For those who respond: CTCL: 9-13 months PTCL: 3-4 months	✓

Accelerated Approvals:

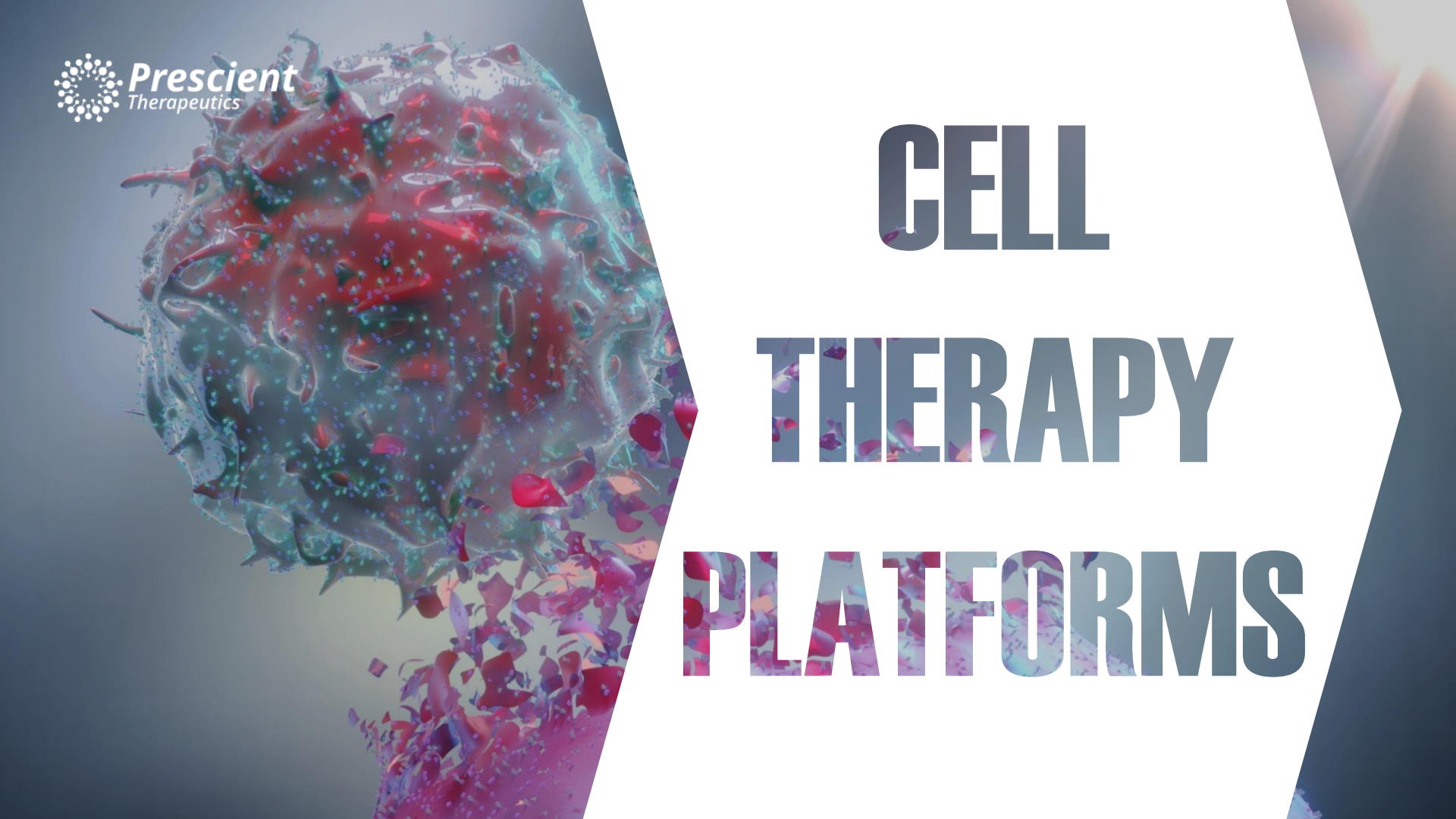
Much faster & cheaper route to market



What does PTX-100's progress mean for PTX?

- Biggest catalyst in company's history, and the culmination of years of work
- Potential Phase 2 registration study (i.e. **the study required to get a drug into the market***)
  - Could **accelerate** clinical development
  - Greatly **truncate the time and money** required to approve PTX-100
- PTX could be the **only ASX-listed biotech company** with a drug in a potential registration study
- Orphan Drug Designation from FDA **protects PTX-100 for 7 years** post approval

* Subject to trial meeting or exceeding endpoints required by regulatory body at the end of the Phase 2 study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Therapeutics
CELL
THERAPY
PLATFORMS

Platforms to overcome CAR-T's key challenges

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	OmniCAR	CellPryme
Safety & Control	✓	-
Targeting	✓	-
Escape	✓	-
Production efficiency	✓	-
Exhaustion	✓	✓
Trafficking	✓	✓
Tumor penetrance	✓	✓✓
Tumor microenvironment	✓	✓✓

=

Safer

More effective

Accessible & affordable

Prescient Therapeutics

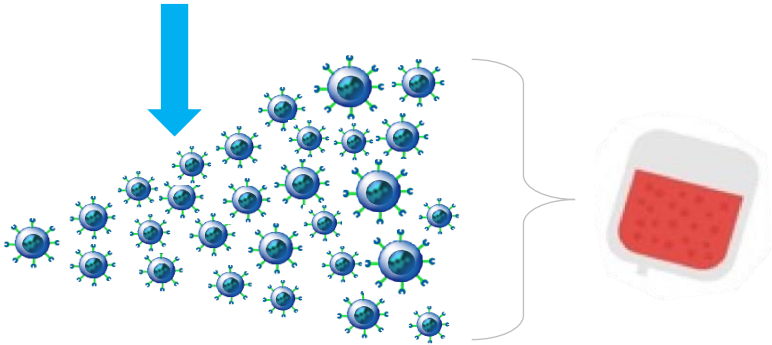
CellPryme

CELL THERAPY ENHANCEMENTS

CellPryme: enhancing cell therapies in two ways

CellPryme-M

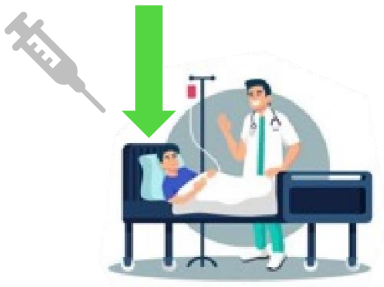
MANUFACTURING ENHANCEMENT



Non-disruptive additive during cell manufacturing

CellPryme-A

ADJUVANT THERAPY

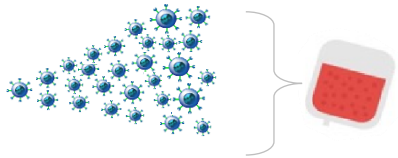


Administered to patient concurrent with cell therapy

CellPryme-M

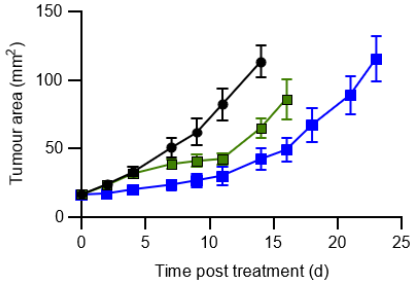
Prescient Therapeutics

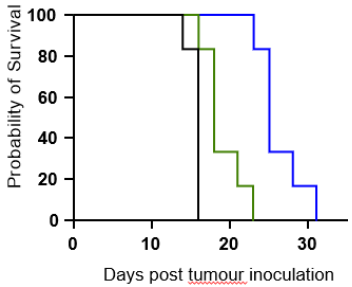
MANUFACTURING ENHANCEMENT

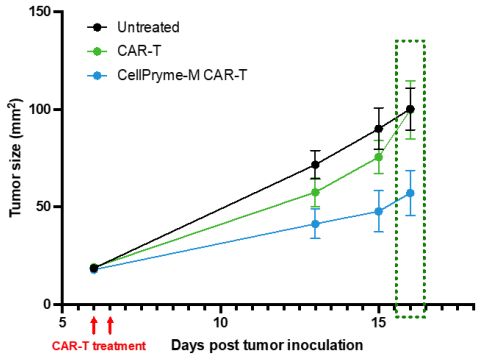


PRODUCES SUPERIOR CELLS

- 50% more “youthful” Tcm cells
- Last longer; potent killing
- Doubles helper Tcells
- **Doubles tumour control & survival**







CellPryme-A

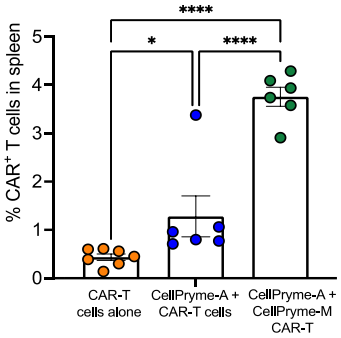
Prescient Therapeutics

ADJUVANT THERAPY

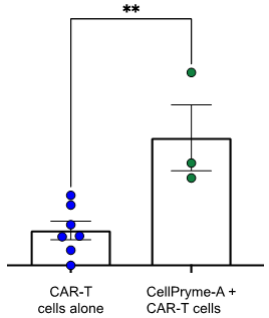
BREACHES THE CANCER'S CASTLE WALLS

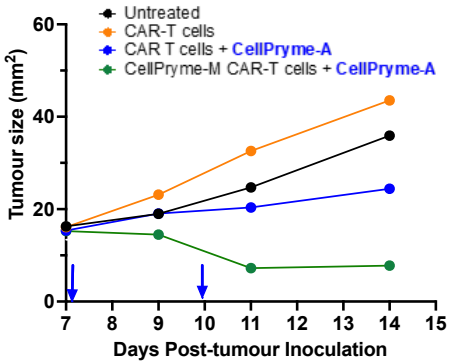
- 9X more CAR-T cells
- 4x penetration the cancer's protective barriers
- **Very strong cancer killing synergies with CellPryme-M!**

↑9x expansion



↑4x tumour penetration





CellPryme progressing externally

- PTX in advanced discussions with several potential partners for CellPryme-M that are progressing simultaneously.
- Discussions have progressed from confidential due diligence to materials transfer agreements, so these parties can test CellPryme-M in their own processes and/or alongside their own proprietary products.
- Naturally, each process or new combination requires a degree of optimisation, and PTX is working with each party through this process.
- PTX is manufacturing more clinical grade CellPryme-A ahead of first-in-human clinical studies in combination with CAR-T therapies. PTX continues to explore third-party opportunities to evaluate CellPryme-A clinically, despite current challenges in cell therapy market.
- PTX has been invited to present CellPryme at the upcoming CAR-TCR Summit in Boston, MA in September in front of many potential collaborators and customers. This will aid momentum of external discussions.

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OmniCAR

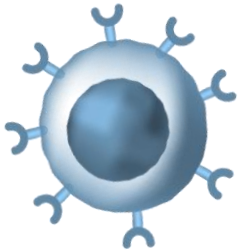
Universal, Next-Gen cell therapies

Penn
University of Pennsylvania

University of Oxford

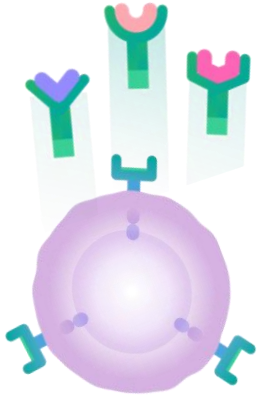
OmniCAR: modular “plug & play” cells

Conventional CAR-T

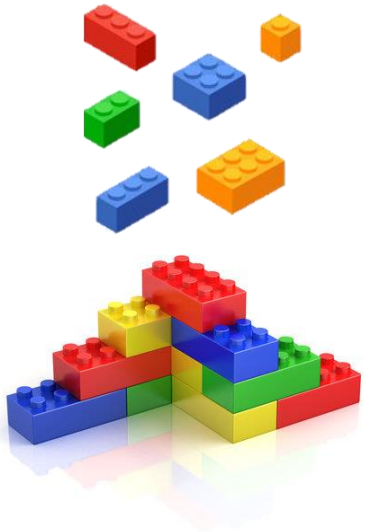


- Static
- Single target
- Uncontrollable

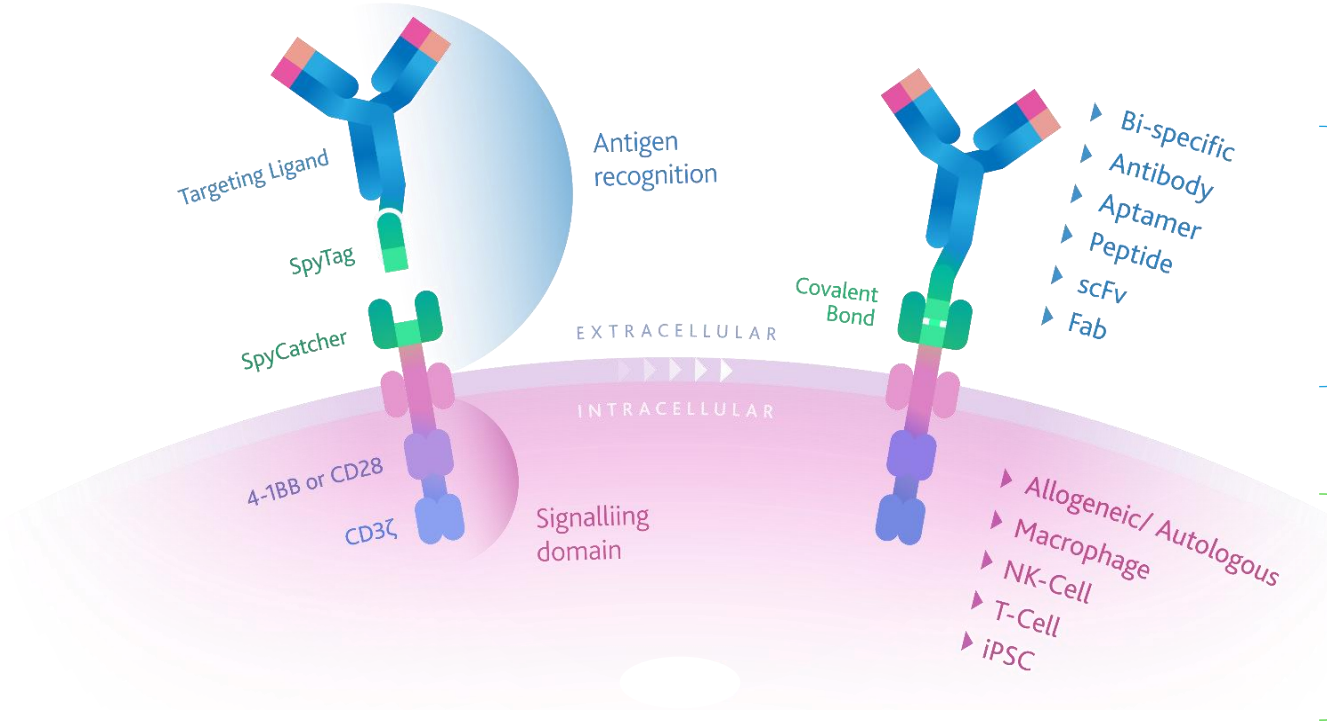
OmniCAR



- Adaptable
- Multi-target
- Controllable



Any immune cell → to any target



OmniCAR can use any type of **targeting ligand…**

…with any **immune cell**

Adapted from Powell, DJ et al, JACS; 2020

OmniCAR redesign efforts progressing

- PTX team has been addressing cytotoxicity of unarmed OmniCAR cells. This is essential for clinical development.
- A development effort to try to address the issue has been underway throughout 2024. Involves PTX team; Peter Mac & CSIRO across multiple disciplines including cell biology; protein engineering and bioinformatics.
- PTX still believes that modularity can play a key role in the future of cell therapy, and that it has not lost much ground during the current cell therapy sector malaise.

PTX strategically positioned in an evolving field

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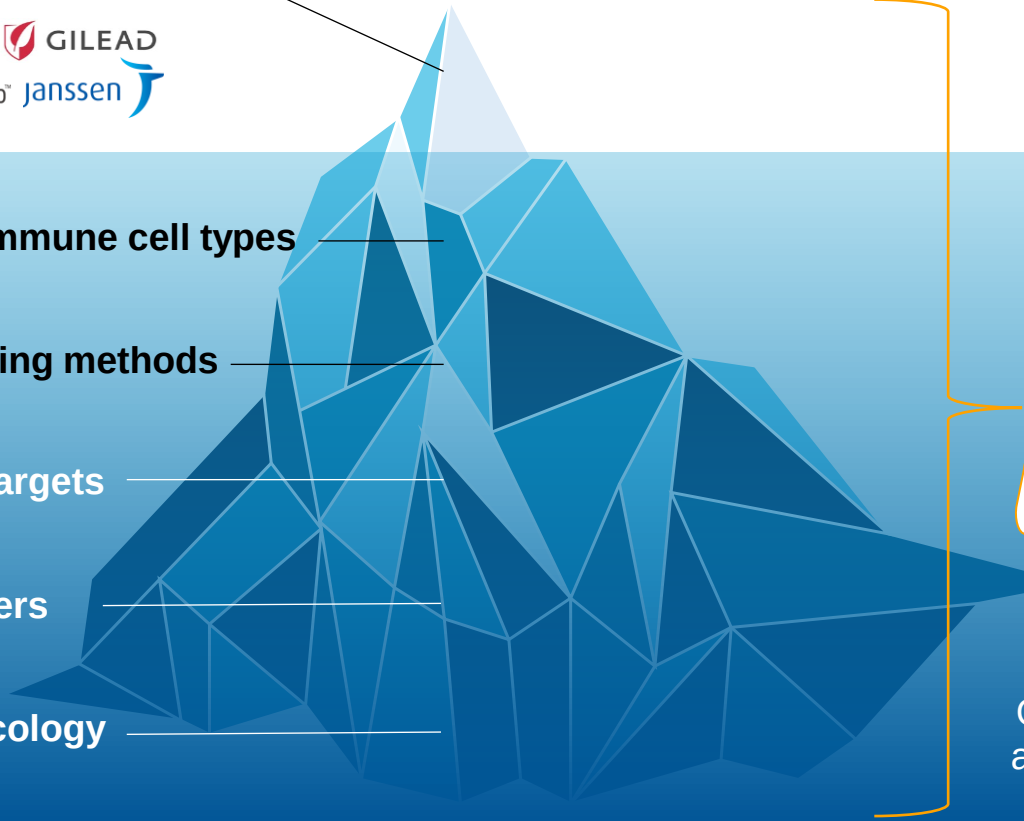
Current generation CAR-Ts

NOVARTIS GILEAD Bristol Myers Squibb janssen



Emerging immune cell types

Manufacturing methods

Emerging targets

Other cancers

Beyond oncology

CellPryme

OmniCAR

Can enhance existing and emerging cell therapies

Other cell therapy companies are **potential customers, not competitors**

Summary

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On the verge of a major inflection point

- Starting Ph2 potential registration trial in 2024
- Encouraging data in an area of unmet need

2 CellPryme OmniCAR

Lower risk exposure to cell therapy sector

- Improves 3rd party cell therapies
- Agnostic on cell type and targets

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Well capitalised to deliver on milestones

Cash and equivalents as at 30 June 2024

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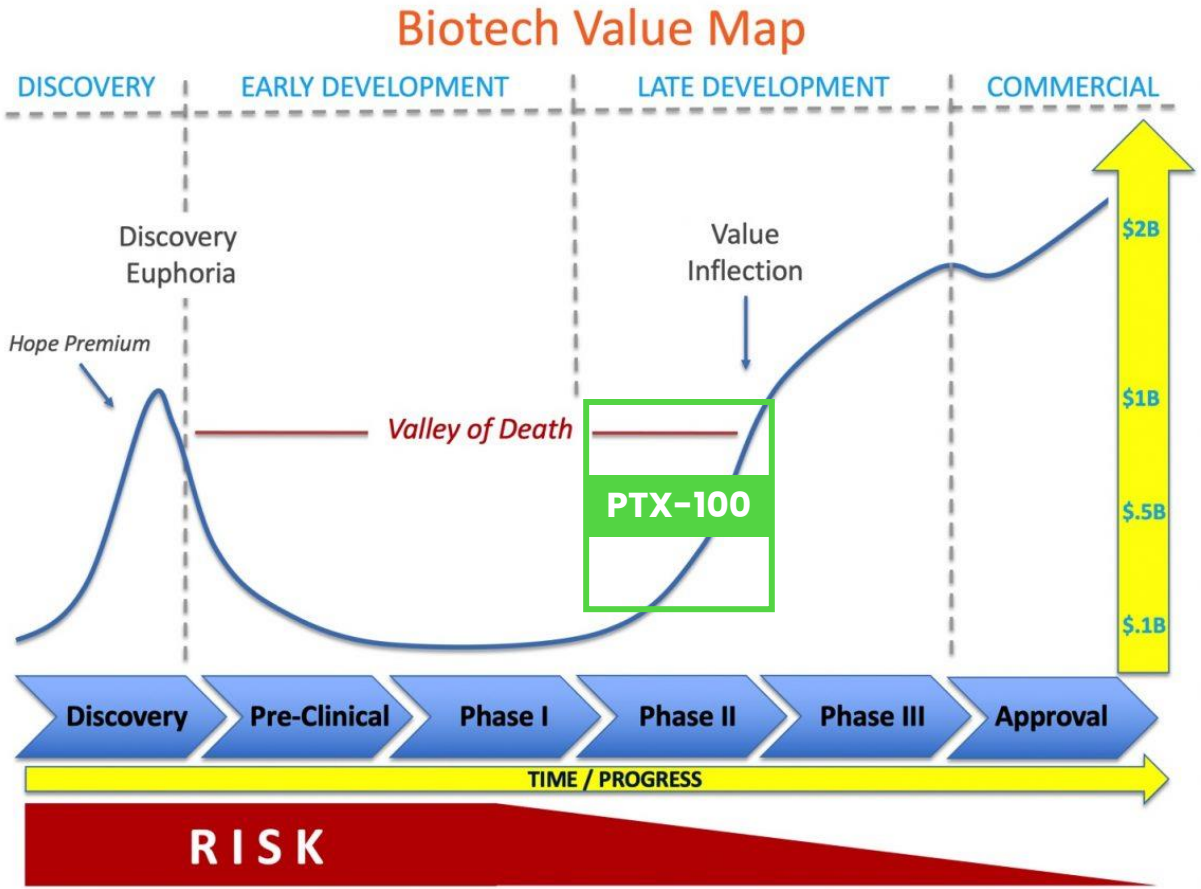

Adapted from Future Healthcare Today , 2021


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THANK
YOU
ASX: PTX