FivepHusion

Investor Presentation
March 2025

OPTIMISED CANCER THERAPEUTICS

Raising new capital to prepare for registration trials

Dr Christian Toouli, CEO & Managing Director
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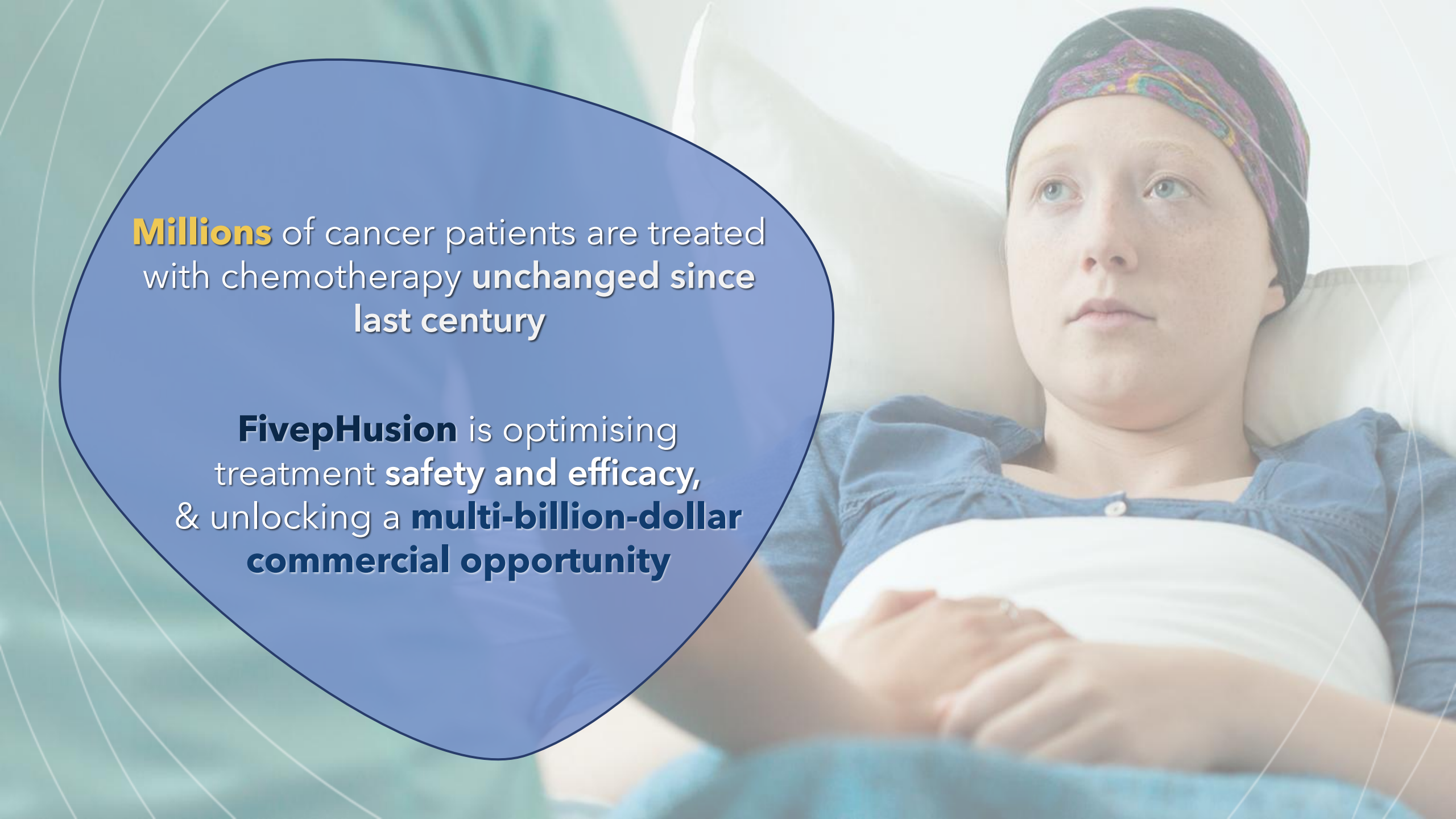
Millions of cancer patients are treated with chemotherapy **unchanged since last century**

FivepHusion is optimising treatment **safety and efficacy,** & unlocking a **multi-billion-dollar commercial opportunity**



EXECUTIVE SUMMARY

Deflexifol®: A next-generation, best-in-class treatment

A new & optimised **standard of care** therapy

- Positioned to **replace standard therapy** in solid tumours
- Primary indication of **1st line metastatic colorectal cancer**
- Sales revenue potential **≥US$1B**

Broad therapeutic utility & **market opportunities**

- **Significant upside** commercial potential
- High need indications such as **paediatric brain cancers**
- Other pancreatic, gastric, breast, head & neck cancers

Technically low-risk & clinically advanced

- 5x surrogate pII trials support **increased survival benefit**
- **Fast-tracked, low-risk** regulatory pathways – market launch in 2029
- **Low-cost,** scalable manufacture within Australia, with access to expertise + global supply chains
- **Endorsed** by leading oncologists
- **Granted composition of matter IP** + patent pipeline

RAISING UP TO AU$20M TO PREPARE FOR REGISTRATION TRIALS

PRICED FOR A 3-5X INVESTMENT RETURN
VIA IPO IN 2026

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STRONG & EXPERIENCED LEADERSHIP

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MBBCh; FFPM; MBA; GAICD

Iain Ross
Non-Executive Director
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Strategic collaborations bringing global resources, capabilities and expertise

Syneos Health · Pfizer CentreOne · allarity THERAPEUTICS · Children's Cancer Institute · University of Wollongong Australia · University of South Australia · FB RICE The IP Navigators · PHARMALEX CONFIDENCE BEYOND COMPLIANCE

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Advising on the clinical strategy and trial design for Deflexifol® registration for use in adult cancers

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University of Sydney · NHMRC Clinical Trials Centre

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Monash University · theAlfred

FOUNDER ADVISORY BOARD

Inventors of Deflexifol® contributing expertise to ongoing development

Prof. Philip Clingan OAM

Senior Prof. Marie Ranson

Emeritus Prof. John Bremner AM

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Deflexifol®: A New Standard of Care

Metastatic colorectal cancer (mCRC)

Typically treated palliatively, with up to only ~55% response rate & ~30-month survival

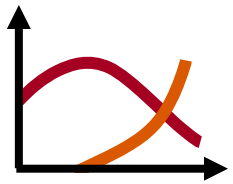
5-fluorouracil (5-FU) + leucovorin (LV) are the "backbone" of mCRC therapy

~95% of patients receive 5-FU/LV

The treatment backbone for the foreseeable future[1]

5-FU + LV = synergistic,
but **chemically incompatible**

Administered sequentially to "work around" incompatibility



Limited co-exposure
Sub-optimal efficacy

Deflexifol® successfully co-delivers 5-FU + LV

Enhances + optimises treatment to **significantly improve outcomes** for patients

1 + 1 = 3

[1] According to KOL opinion & competitive landscape analysis, and as reviewed by Glimelius *et al.* 2021, *Cancer Treat Rev* 98:102218.

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TWO CLINICAL TRIALS CONFIRM IMPROVED SAFETY AND EFFICACY

59 end-stage patients with a variety of solid tumours[1]

- **Reduced toxicity and improved tolerability**
- **Effective disease control in the majority of patients** despite failing all prior therapies (including 5-FU)
- Supported by five independent phase II studies[2] demonstrating **improved anti-tumour activity and significant survival benefits**

Deflexifol® monotherapy

64-69% disease control rates

Across two dose-escalation studies in **end-stage, heavily pre-treated** patients

vs.

Approved mCRC monotherapies

41% for regorafenib (US$580M sales in 2023)

&

44% for Lonsurf® (US$550M sales in 2023)

[1,2] Deflexifol™ publications, conference proceedings and supportive literature can be found at: https://fivephusion.com/publications/.

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AIMING TO BE THE FIRST APPROVED DRUG FOR PAEDIATRIC EPENDYMOMA

PAEDIATRIC EPENDYMOMA	• **The third most common brain cancer in children** • Peak incidence <4 years of age
CURRENT TREATMENT	• Surgical resection and adjuvant radiotherapy • **There are no approved drug therapies**
RATIONALE	• **US trial[1]: 5-FU activity in children that had failed prior therapy** • **Deflexifol® is safer and more efficacious than 5-FU alone**
DEFLEXIFOL® AT RELAPSE TRIAL (DART)	• **National,** investigating safety and tolerability in children with brain cancer • **A safe & tolerable dose confirmed, encouraging reports of extended treatment durations**

Orphan indication with a fast path to approval

[1] Wright et al. 2015, *Neuro Oncol.*, 17(12):1620-27

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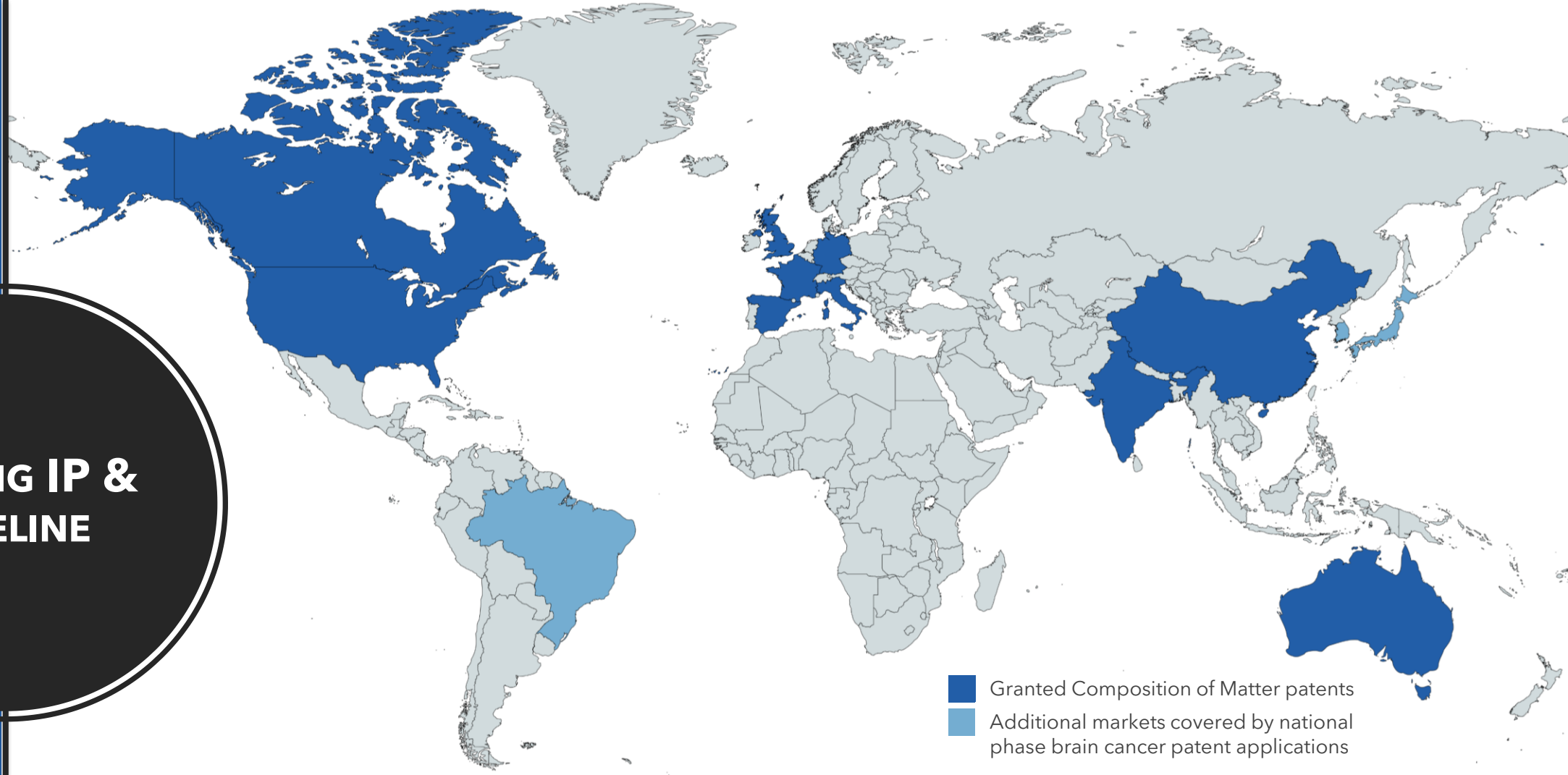
Strong IP & Pipeline



- **Granted composition of matter**
- Patents in prosecution
- **New composition** filing early 2025
- IP pipeline 2025/26

expected exclusivity to

>2045

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SIGNIFICANT COMMERCIAL OPPORTUNITIES

Deflexifol® addresses global markets

- **1.9M colorectal cancer** incidence; 20-30% diagnosed metastatic[1]
- **US$13B** mCRC market[2], **majority receive 5-FU/LV**[3]
- FDA confirmed immediate **path to 1st line treatment**
- **Strong pharmacoeconomic value** / basis for **premium pricing**

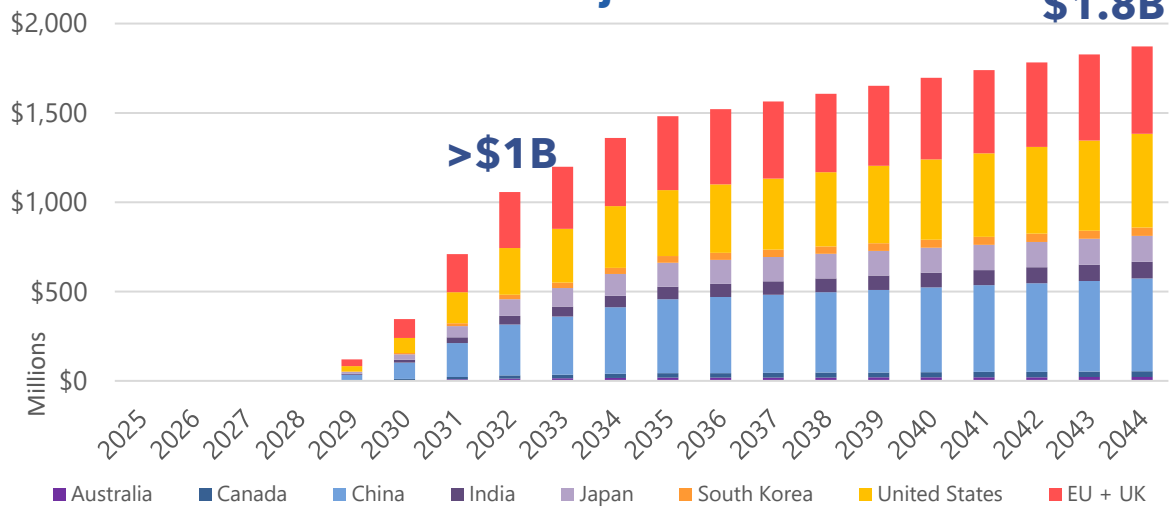
Upside:

+ Paediatric brain cancer: **US$1.84B**[4] → Adult brain cancer
+ Replace 5-FU+LV across solid tumour indications = **>5M patients**

Interest from prospective regional licensing partners

Precedents: **$22M** Upfront payment **$192M** Total payments *(US$ average)*

Deflexifol® Projected Sales[5]



Path to Substantial Value

- **De-risked & accelerated regulatory pathways** to market
- Commercial launch: **2029**
- Projected global peak sales: **US$1.8B**

[1] Global Cancer Observatory 2020, Cancer Today; GLOBOCAN 2020
[2] 2025 Colorectal Cancer Market Insight, Epidemiology And Market Forecast - 2034
[3] Glimelius et al., 2021, *Cancer Treatment Reviews* 98:102218
[4] Market Research Future 2023
[5] Indications: drug sales for the treatment of mCRC, ependymoma, CRC, breast, gastric, pancreatic

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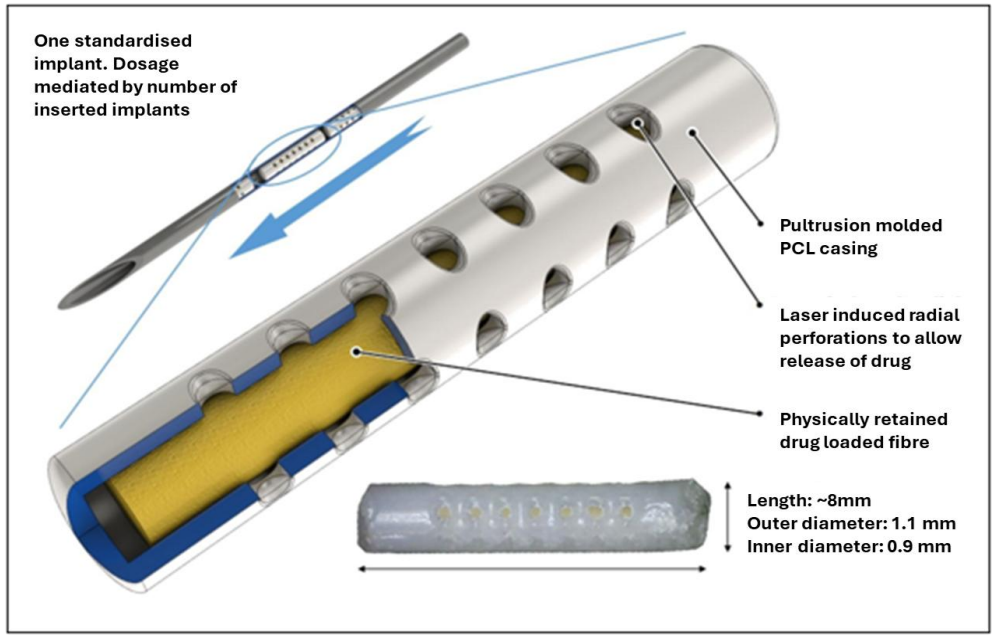
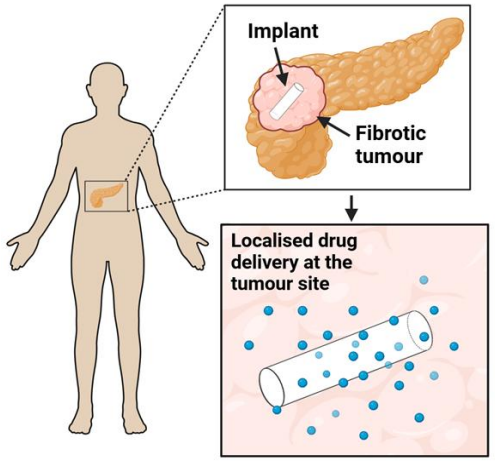
ResectAssist™: Biodegradable drug-eluting implant
(Pipeline opportunity)

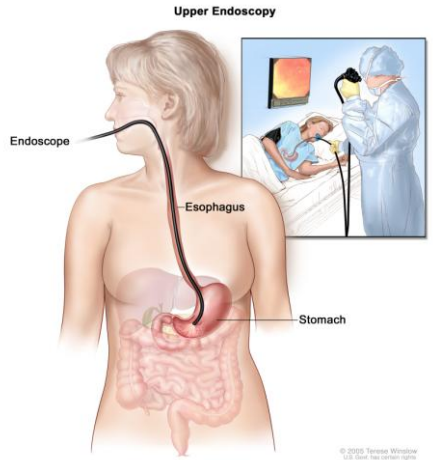
- **Novel platform technology**
- **Intra-tumoural drug delivery** via **standard endoscopy**
- **Manufactured using FDA-approved biomaterials**
- **Diverse drug payloads** inc. approved medicines and in-development drugs

↑ higher focused dose

↓ lower systemic toxicity







Strategic Lead Program – Pancreatic Cancer

- ResectAssist™- FOLFIRINOX

  → *Downstaging tumours to resectable with curative intent*

- Major unmet medical need; $7B[3] market opportunity
- Granted composition of matter patents & IP pipeline
- Awarded Federal Government $500K AEA Ignite grant

UNIVERSITY OF WOLLONGONG AUSTRALIA

[1] Wade et al., 2020, Adv. HealthcareMater. :Nov;9(21):e2001115; [2] Minaei et al., 2024, J Immunother Cancer 2024;12(Suppl 2):A1–A1683;
[3] Polaris Market Research 2022 – pancreatic cancer market in 2030

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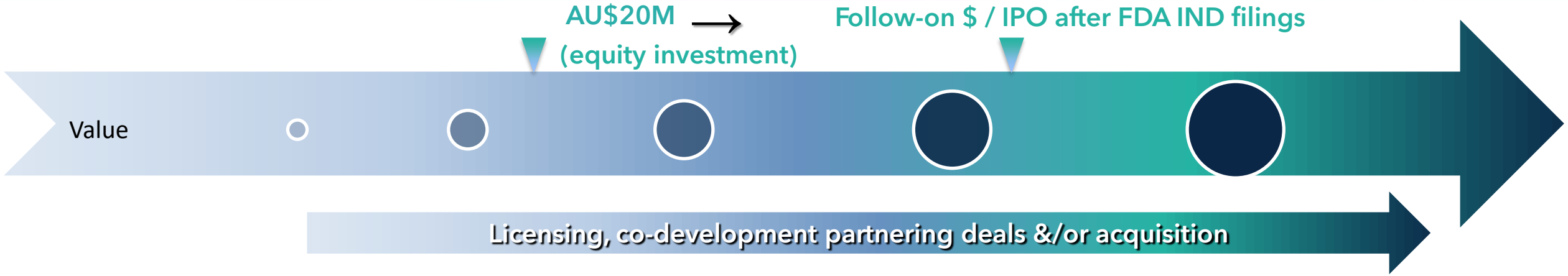
VALUE CREATION STRATEGY



Value catalysts	2025	2026	2027	2028	2029
mCRC	Ethics approval	pI/II dose confirmation → FDA	pIII Registration Trial		Market launch
Paediatric brain cancer	Phase 1/2 trial ongoing	FDA	Registration trial		Market launch
Other Cancers			Phase 1b trials (other 5-FU treated cancers)		
ResectAssist™ -FOLFIRINOX (pipeline opportunity)	Manufacturing & non-clinical development		Phase 1b trial: pancreatic cancer		

All development steps and timelines are indicative.

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USE OF FUNDS

Raising up to AU$20M in new equity funding to support Deflexifol® development & commercialisation

A follow-on/IPO capital raise is planned for 2026 following Investigational New Drug (IND) designations for the treatment of 1st-line mCRC and paediatric ependymoma.

Deflexifol® registrational trials planned in initiate in late 2026, with commercial launch planned for 2029.

New funding will support:

- Phase Ib/IIa **mCRC & paediatric brain cancer trials** – ethics approved and poised to commence.
- **Commercial formulation refinement** and **scale up GMP manufacturing**.
- **Global regulatory agency IND approvals** – both indications.
- **Pipeline opportunities** including new indications treatable by Deflexifol® and the ResectAssist™ platform technology.
- **Pre/post registration planning** including health economics, pricing, reimbursement and sales strategies.
- Preparation of FivepHusion for a **planned IPO in 2026**.

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Optimising Cancer Therapeutics for Patients

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Appendix

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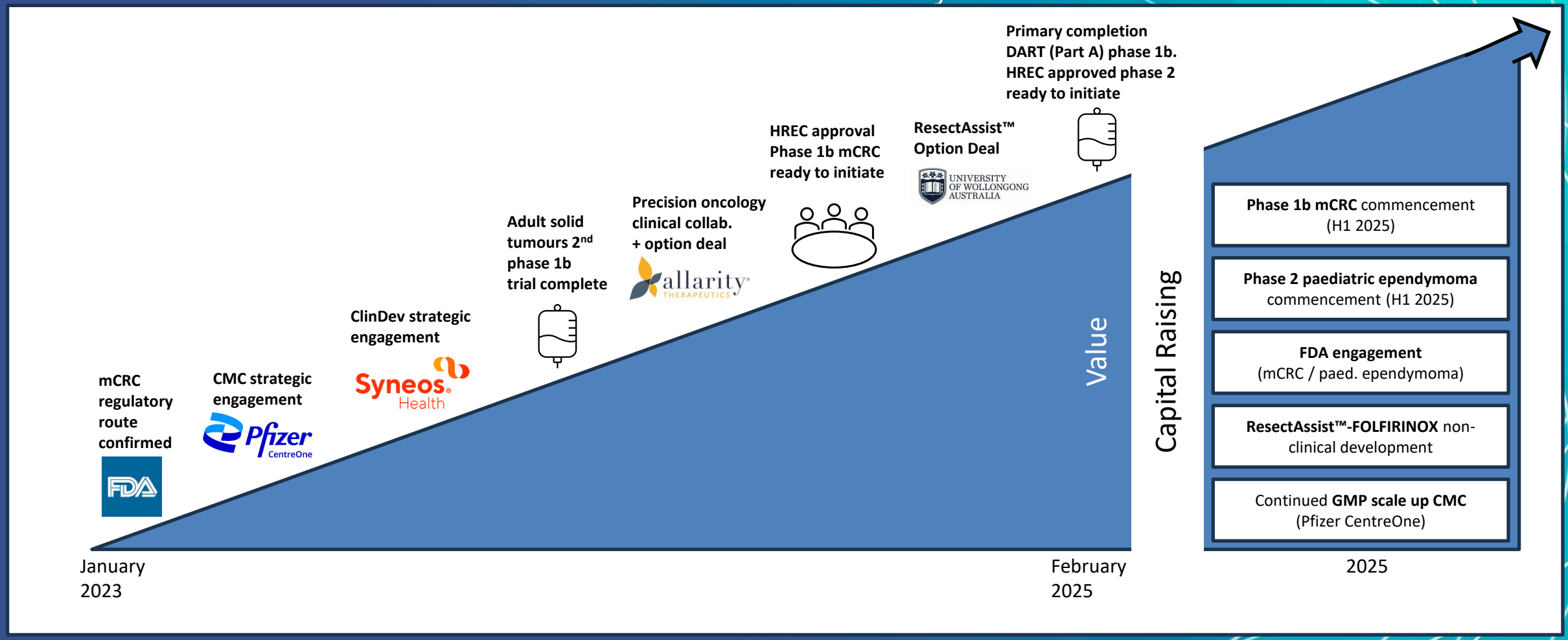
Continuous value creation from 2023 – 2025 & beyond



DEFLEXIFOL™ IS EFFICACIOUS AFTER 5-FU + LV FAILURE IN END-STAGE CANCER PATIENTS

- In two trials, heavily pre-treated patients **experienced benefit from optimised 5-FU/LV delivery**
- Activity after repeated failure of treatment with the same drugs - Indicates Deflexifol® superiority
- In the most recently completed trial^: Disease control: 9/13 (69%) evaluable patients; median PFS: 28.2 weeks. Examples:

Metastatic colorectal cancer
male, 59 years

Failed two prior lines
- FOLFOX
- FOLFIRI + bevacizumab

Deflexifol™
525 mg/m² bolus + 3000 mg/m² infusion

Stable Disease
5 months

Pancreatic Cancer
female, 75 years

Failed two prior lines
- FOLFIRINOX
- Gemcitabine/abraxane

Deflexifol™
525 mg/m² bolus + 3000 mg/m² infusion

Stable Disease
6 months

Metastatic colorectal cancer
male, 61 years

Failed four prior lines
- FOLFOX + bevacizumab
- FOLFIRI
- Panitumumab
- Lonsurf®

Deflexifol™
525 mg/m² bolus + 3800 mg/m² infusion

Partial Response
6 months

^ Patients treated in the FP101A phase Ib/IIa trial (ACTRN12619001533189, completed May 2023). Presented at ASCO GI 2024: Link
FOLFOX = 5-FU, LV & oxaliplatin; FOLFIRI = 5-FU, LV & irinotecan; FOLFIRINOX = 5-FU, LV + oxaliplatin & irinotecan
PFS = Progression Free Survival; Partial response = tumor reduced in size by ≥30%

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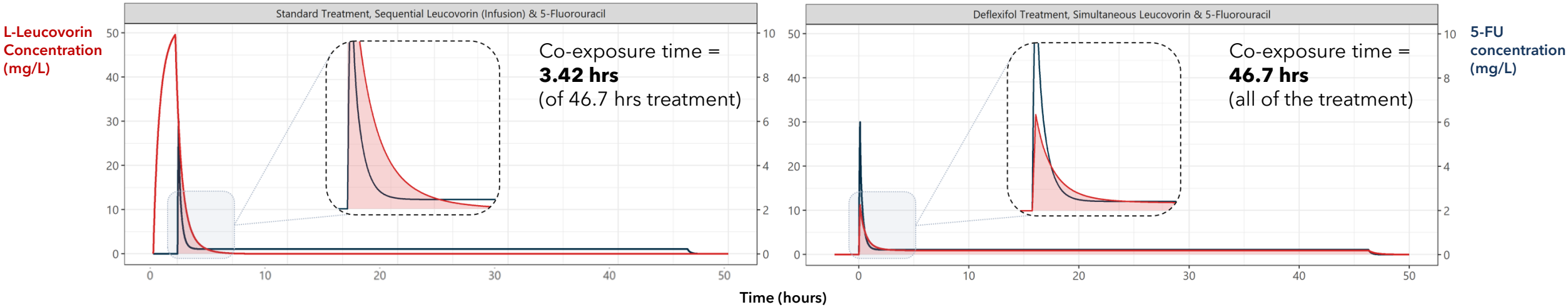
WHY DEFLEXIFOL™ ENHANCES EFFICACY

Deflexifol® co-formulates 5-FU/LV safely with a FDA-approved cyclodextrin to enable maximal tumour co-exposure over the standard 46 hr infusion treatment cycle, enhancing 5-FU activity for **optimal treatment efficacy**

Current Standard of Care
Sub-Optimal Serial Administration

Co-infusion via Deflexifol®
The New Gold Standard of Care™



<10%
5-FU/LV co-exposure

100%
5-FU/LV co-exposure

Modelled pharmacokinetics based on published independent literature:
Maring et al. 2003, *Cancer Chemother Pharmacol.* 51:167
Straw et al. 1984, *Cancer Res.* 44:3114

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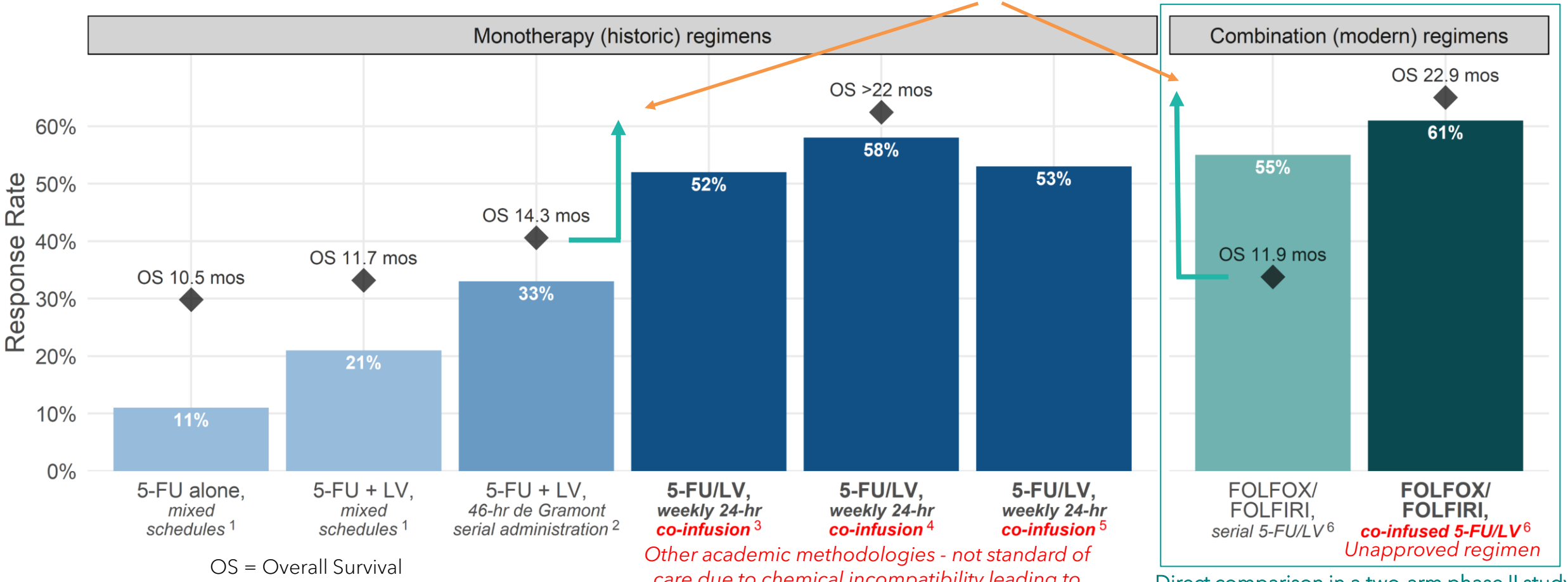
5-FU/LV CO-INFUSION IMPROVES ANTI-TUMOUR EFFICACY

- mCRC 1st line treatment has only incrementally improved over decades
- Independent phase II trials indicate superiority of 5-FU/LV co-infusion (using unsafe / impractical/ unapproved methods)

Precedent for Deflexifol® - which is designed to safely co-infuse 5-FU/LV to enhance efficacy



OS = Overall Survival

Other academic methodologies - not standard of care due to chemical incompatibility leading to safety risks

Direct comparison in a two-arm phase II study

1. Thirion et al. 2004, *J Clin Oncol.*, 22(18):3766-75.
2. de Gramont et al. 1997, *J Clin Oncol.*, 15(2):808-15.
3. Ardalan et al. 1991, *J Clin Oncol.*, 9(4):625-30.
4. Yeh et al. 1997, *Anticancer Res.*, 17(5B):3867-71.
5. Yang et al. 1999, *Cancer*, 85(9):1925-30.
6. Bleiberg et al. 2012, *Acta Gastroenterol Belg.*, 75(1):14-21.

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PHASE 1/2 DEFLEXIFOL® AT RELAPSE TRIAL (DART)

Ongoing investigator-led trial involving paediatric oncology centres across Australia[1]

Paediatric patients with:

- **refractory/relapsed CNS tumours, including ependymoma**
- newly diagnosed **diffuse intrinsic pontine glioma** (DIPG) / **diffuse midline glioma** (DMG) who have completed radiotherapy

Trial Design:

Part A: Open-label, phase I dose escalation

- Between n= 6-24, bolus + infusional Deflexifol® commencing at the adult MTD with dose de-escalation as required

Part B: Phase II refractory or recurrent ependymoma expansion cohort^

- Up to n=10, primary endpoint of Objective Response Rate

<u>Encouraging Deflexifol® activity in patients treated to date</u>

[1] ACTRN12623000104651 (link)

FP101B: HREC APPROVED PHASE 1B/2A TRIAL DESIGN (2025 STUDY^)

Dose exposure / response confirmation for Deflexifol® when combined with oxaliplatin + bevacizumab

- 1st line unresectable mCRC
- 40 – 50 patients; trial duration ~12 months
- Allarity Therapeutics collaboration: Blinded evaluation of DRP®-5FU CDx predictive ability

- **Primary endpoints:** Safety and tolerability of Deflexifol® when combined with oxaliplatin and bevacizumab
- **Secondary endpoints:**
  - Pharmacokinetics of Deflexifol® when combined with oxaliplatin and bevacizumab, DRP®-5FU evaluation
  - ORR, PFS*

PART A: Dose Escalation Cohorts (3 + 3)
(9-18pts, 3 trial sites; ~6 months∅)

OXALIPLATIN
85 mg/m²

BEVACIZUMAB
5 mg/kg

+ **DEFLEXIFOL® BOLUS# 400 mg/m²** +

DEFLEXIFOL® INFUSIONΩ Dose:

3400 mg/m²

No DLTs

3000 mg/m²

No DLTs

2400 mg/m²

3 patients per cohort + an additional 3 patients at the final dose

PART B: Expansion Cohort
(~30 pts, 6 - 8 trial sites; ~6 months∅)

OXALIPLATIN
85 mg/m²

BEVACIZUMAB
5 mg/kg

+ **DEFLEXIFOL® BOLUS 400 mg/m²** + **DEFLEXIFOL® INFUSION Part A MTD**

^ Trial design approved by Bellberry HREC in April 2024. Trial planned to commence Q1 2025, pending successful capital raising
*ORR = Objective Response Rate; PFS = Progression Free Survival, MTD = Maximum Tolerated Dose, DLT = Dose Limiting Toxicity
∅ Time frame to expected primary completion
Deflexifol® bolus = 400 mg/m² 5-FU + 27 mg/m² LV;
Ω Deflexifol® infusion dose escalation = 2400 mg/m² 5-FU + 160 mg/m² LV (equivalent to the current standard 5-FU dose) up to the currently declared MTD of 3400 mg/m² 5-FU + 227 mg/m² LV

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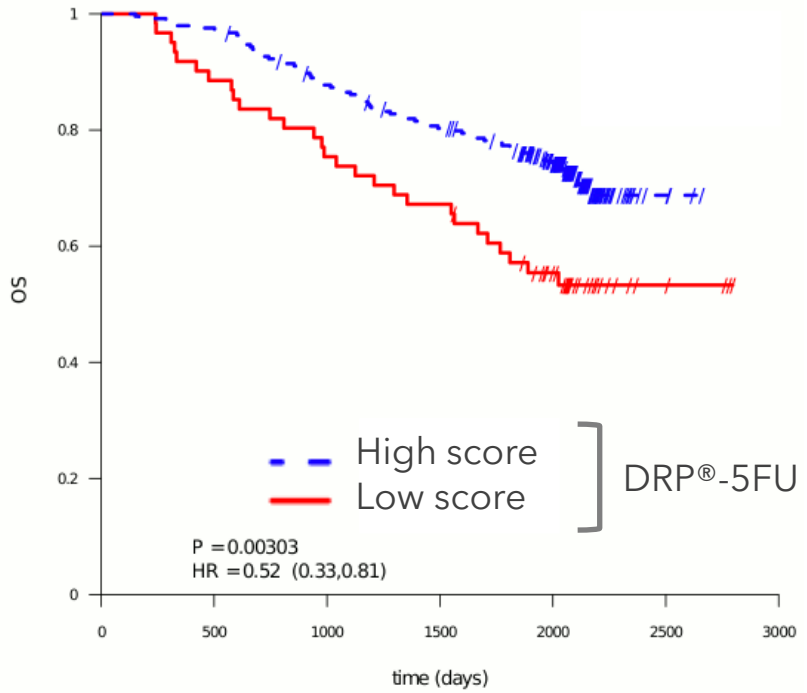
EXPLORING PRECISION-ONCOLOGY (AUGUST 2023 DEAL)

- **Drug Response Predictor (DRP®) companion diagnostics**, highly validated via >35 clinical trials[1]
  - Proprietary DRP® algorithm applied to tumour biopsy gene expression data sets
  - Validated drug-specific response signatures, 80+% predictive response accuracy
  - 2-5 fold increase in response: *predicted* sensitive vs *predicted* resistant tumours
- **DRP®-5FU retrospectively validated to predict response and overall survival to 5-FU** treatment in late-stage CRC and mCRC [2,3]
- **Collaboration to evaluate the DRP®-5FU** and other DRP® companion diagnostics in the upcoming FP101B phase 1b/2a trial of Deflexifol® in 1st line mCRC
- **Option right to negotiate an exclusive license** to commercialise the DRP®-5FU and other DRP® companion diagnostics for Deflexifol™
- **Potential to personalise cancer treatment** for patients most likely to benefit from Deflexifol®

Overall Survival of Stage III Colon Cancer Patients Treated with 5-FU + LV [2]



n = 307 stage III CRC patients from PETACC-3 trial

1. www.allarity.com 2. Buhl et al., 2016, PLoS ONE 11(5): e0155123; 3. Buhl et al., 2019, Annals of Oncology, 30(5):v242; OS = Overall survival

REGISTRATION TRIAL: DRAFT PLAN FOR PHASE III TRIAL (Q4 2026)

1st line treatment of unresectable mCRC

- International, multi-centre registration trial (2026 – 2028)
- Designed to demonstrate that as a treatment for first-line unresectable mCRC,

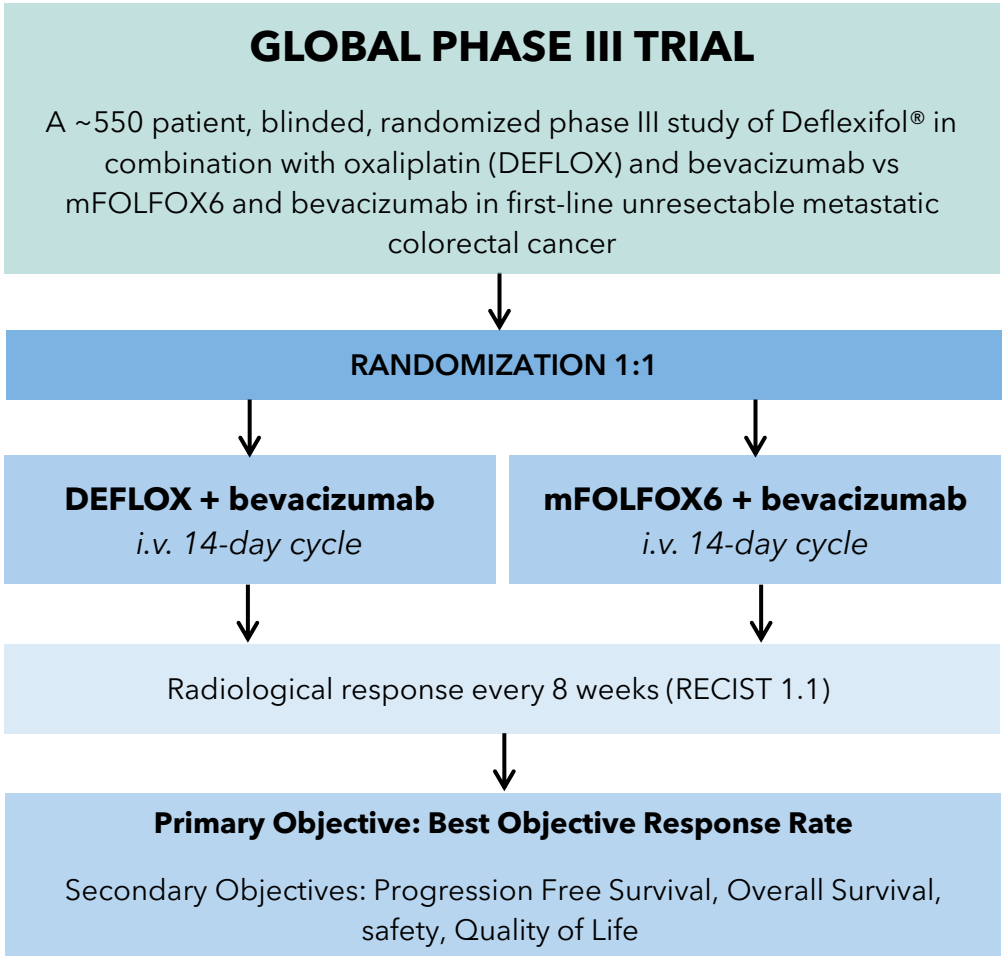
  Deflexifol® in combination with oxaliplatin and bevacizumab (DEFLOX)

  is superior in efficacy to*

  the standard of care mFOLFOX6 + bevacizumab regimen

<u>Rationale for superior efficacy over standard of care</u>

- *Optimised 5-FU/LV co-exposure*
- *Higher 5-FU dose*



* Considering regulatory and commercial factors, this trial design is to be refined and confirmed based on independent expert feedback from KOL oncologists, clinical scientists and regulatory specialists, together with consultation with the FDA, EMA, NMPA and potentially other regulators

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EPENDYMOMA SENSITIVITY TO 5-FU

Ependymoma (EPN) = 3rd most common paediatric brain tumour [1]

EPN cell lines have significantly lower *thymidylate synthase* expression levels [2,3] → **increased 5-FU sensitivity**

Supratentorial
~1/3 of childhood EPN [1]

Posterior fossa (PF)
~2/3 of childhood EPN [1]

All partial responders in the St Jude 5-FU trial had primary PF-EPN [4]

PF-B = ~10-15% of PF-EPN [1]
- Mostly older children & adults

PF-A = ~85-90% of PF-EPN [1]
- Predominantly younger children
- Frequent gain of chromosome arm 1q (1q+) [5]
  - ~20% at presentation
  - ~50% at first recurrence

INCREASINGLY HIGH RISK
(Younger age, PF-A & 1q+ are negative prognostic factors)

PF-A 1q+ cell lines demonstrate:
- Repressed p53 (tumour suppressor) activity **that is restored by 5-FU**
- Significantly higher expression of *UCK2,* a 5-FU 'activating' enzyme → **increased 5-FU sensitivity**

Compared to PF-A 1q wild-type cells [6]

[1] Zaytseva *et al.* 2021, *Cancers* 13(19):4954.
[2] Atkinson *et al.* 2011, *Cancer Cell* 20(3):384-99.
[3] Donson *et al.* 2018, *Mol Cancer Ther.* 17(9):1984-94.
[4] Wright *et al.* 2015, *Neuro Oncol.* 17(12):1620–27.
[5] Donson *et al.* 2023, *Neuro Oncol.* 25(10):1854-67.
[6] Griesinger *et al.* 2024, *Clin Cancer Res.* 30(8):1544-54.

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EPENDYMOMA AND STRATEGIC OPPORTUNITIES

Incidence of 4.3 per million across all age groups in the US[1], varies slightly but overall consistent across geographic regions

Paediatric orphan disease attracts regulatory benefits

Orphan market/data exclusivity in major markets:

10 years in Europe, South Korea and Japan, and 7 years in US

Paediatric extensions to all granted patents / exclusivities:

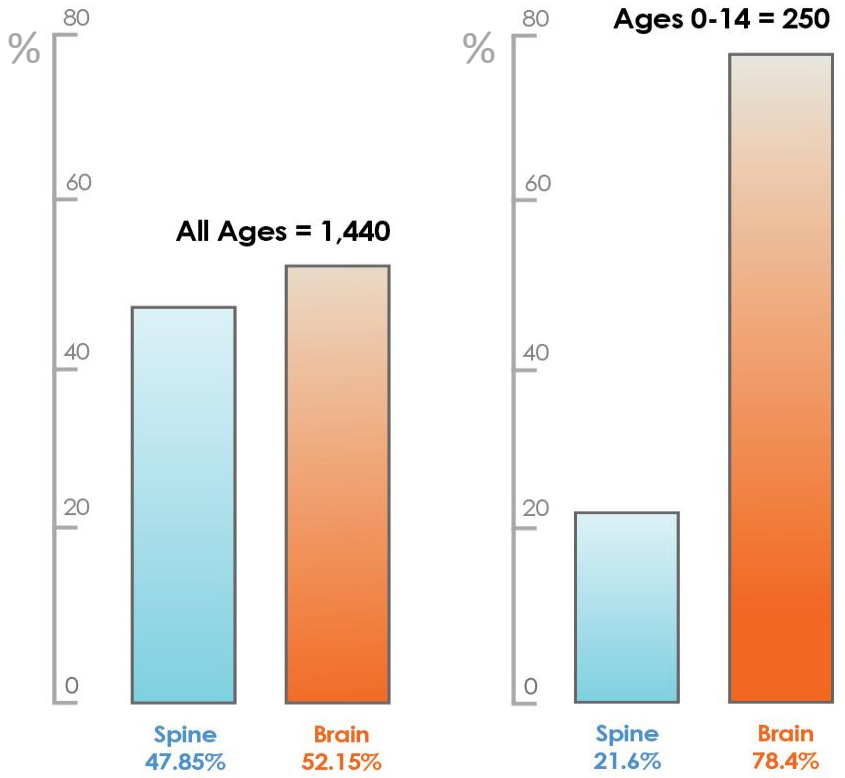
+2 yr exclusivity in EU, +1 yr exclusivity in South Korea

+6 month extension to USA patent

Paediatric orphan disease registration **enhances pricing and sales revenue potential in other indications,** i.e. mCRC

Ependymoma clinical data provides a foundation on which to potentially investigate other brain tumour indications

Estimated New Cases in 2016 in the US [2]



*DATA EXTRACTED FROM Ostrom, Q.T., Gittleman, H., Fulop, J., et al (2015). CBTRUS Statistical Report: Primary Brain Central Nervous System Tumors Diagnosed in the U.S. in 2008-2012. Neuro-Oncology, Vol 17.

[1] Ostrom et al. 2016, *Neuro Oncol.*, 18(supp_5):v1-v75.
[2] CERN Foundation 2016, Ependymoma Statistics.

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