FivepHusion

AusBioInvest 2024

Raising new capital to prepare for registration trials

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OPTIMISED CANCER THERAPEUTICS

DESIGNED BY ONCOLOGISTS TO MORE EFFECTIVELY TREAT THEIR PATIENTS

OPTIMISED CANCER THERAPY

Next-generation, best-in-class treatments

Targeted to patient & clinician needs

- **Enhanced efficacy and safety**
- Priority indications
  - **1st line metastatic colorectal cancer**
  - **Paediatric brain cancers**

Designed for global markets

- Sales revenue potential **≥US$1B**
- Broad potential **utility across solid tumours**
- **Significant upside** commercial potential

Lead Asset: **Deflexifol®**

- Founded on 40 years of science supporting **superior clinical efficacy & increased survival benefits**
- **Fast-tracked, low-risk regulatory path** – launch in **2028**
- **Low-cost, scalable manufacture at Pfizer CentreOne**, Melbourne, accessing global expertise + supply chains
- **Endorsed** by leading oncologists
- **Granted composition of matter IP** + patent pipeline

RAISING UP TO $20M TO PREPARE FOR REGISTRATION TRIALS

POTENTIAL IPO IN LATE 2025 / EARLY 2026

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Deflexifol®: A New Standard of Care

Metastatic colorectal cancer (mCRC)

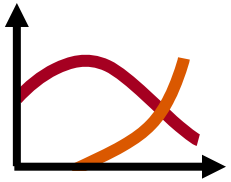
Typically treated palliatively, with up to only ~55% response rate & ~30-month survival

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

~95% of patients receive 5-FU/LV currently and 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

- **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 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)

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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]: promising 5-FU activity in children** after prior therapy failure • Deflexifol® is safer and more efficacious than 5-FU
DEFLEXIFOL® AT RELAPSE TRIAL (DART)	• **National** safety and tolerability trial in children with brain cancer • **Encouraging reports of extended treatment durations**

Pursuing a fast path to approval for a significant unmet medical need

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

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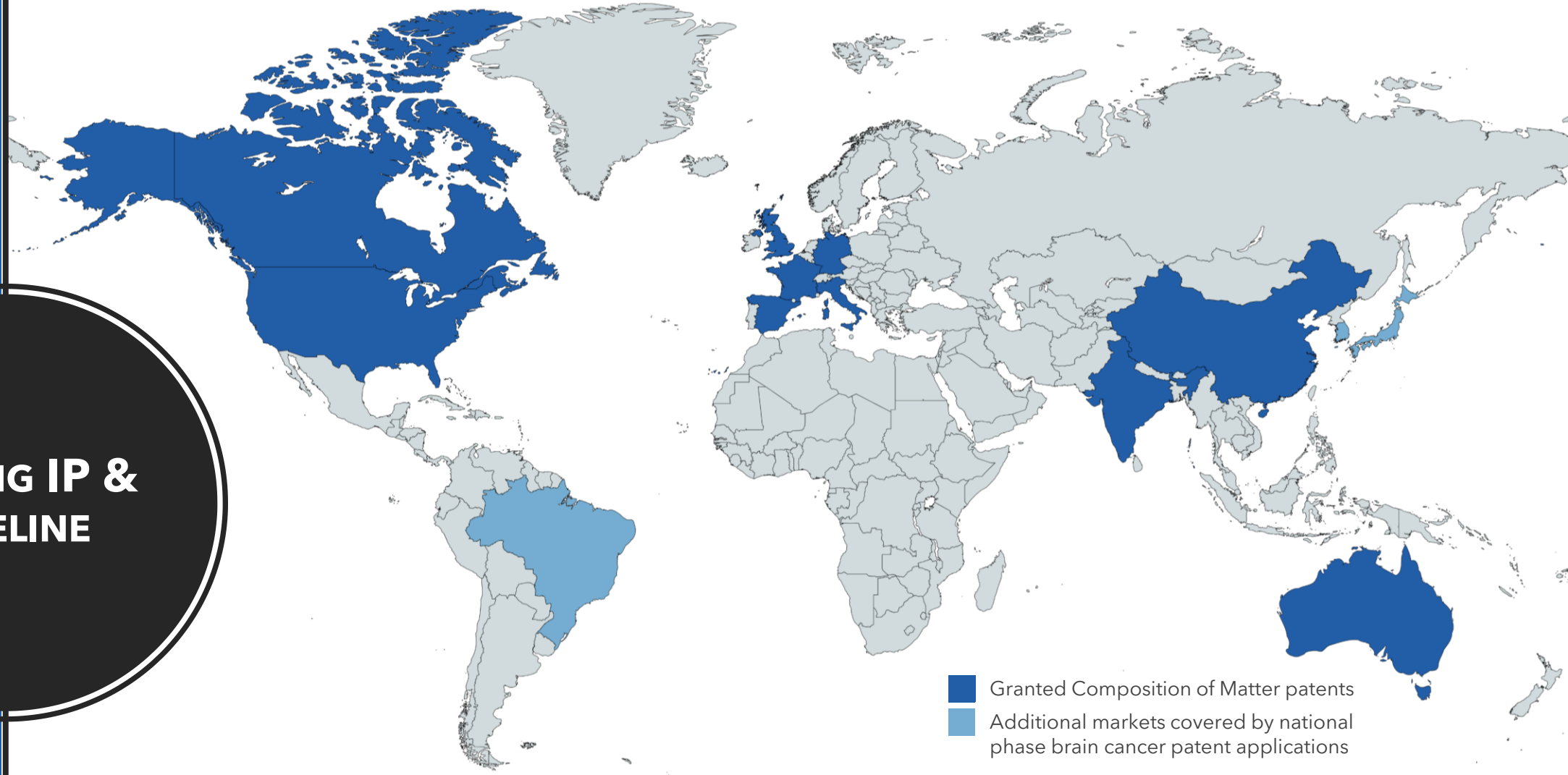
Strong IP & Pipeline



- **Granted composition of matter**
- Patents in prosecution
- **New composition** filing late 2024
- IP pipeline 2025/26

expected exclusivity to

>2044

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SIGNIFICANT COMMERCIAL OPPORTUNITIES

Deflexifol® addresses global markets

- **1.9M colorectal cancer** incidence; 20-30% diagnosed metastatic[1]
- **US$15B** mCRC market[2], **majority receive 5-FU/LV**[3]
- FDA confirmed immediate **path to 1st line treatment**
- **Strong pharmacoeconomic value** / basis for **premium pricing**

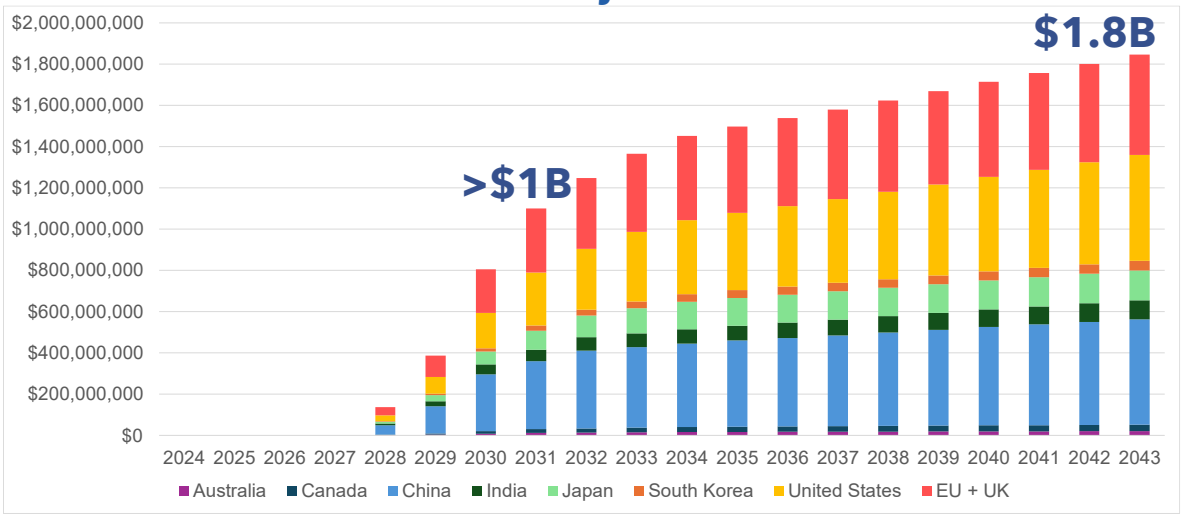
Upside:

+ 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: **2028**
- Projected global peak sales: **US$1.8B**

[1] Global Cancer Observatory 2020, Cancer Today; GLOBOCAN 2020
[2] DelveInsight 2023, Metastatic Colorectal Cancer (mCRC) Report
[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
[6] ASX market valuations as of 09/10/2024

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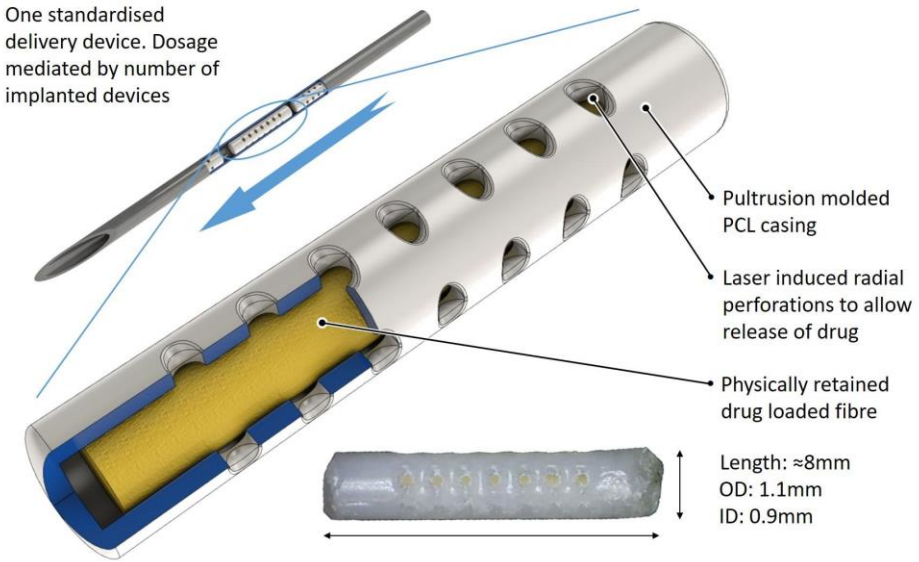
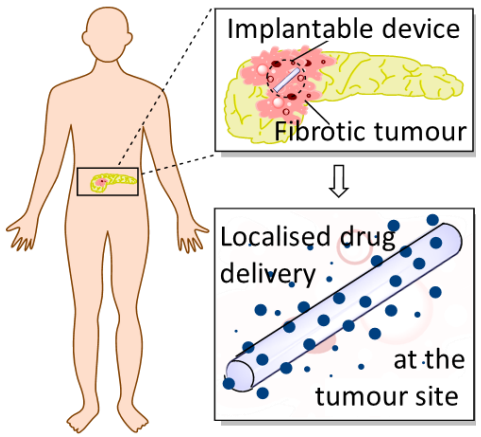
ResectAssist™: Biodegradable drug-eluting implant
(Pipeline opportunity)

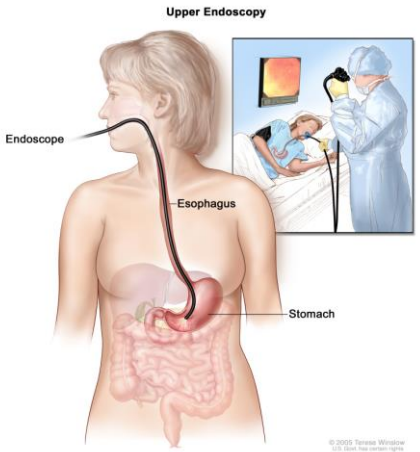
- **Novel platform technology**
- **Intra-tumoural drug delivery** via **standard endoscopy**
- **FDA-approved biomaterials** enabling **tuneable drug elution**
- **Diverse drug payloads** inc. small molecules, biologics, antibody drug conjugates and mRNA therapeutics

↑ higher focused dose

↓ lower systemic toxicity







Strategic Lead Program

- ResectAssist™- FOLFIRINOX for <u>unresectable pancreatic cancer</u>

  → ***Downstaging tumours to resectable with curative intent***

- Granted composition of matter patents & IP pipeline

UNIVERSITY OF WOLLONGONG AUSTRALIA

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VALUE CREATION STRATEGY

Value catalysts	2025	2026	2027	2028
mCRC	New IP, license negotiations; pI/II dose confirmation ✓; FDA ◆	✓ pIII Registration Trial	✓	★ Market launch
Paediatric brain cancer	Phase 1b 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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STRONG & EXPERIENCED LEADERSHIP

BOARD

David Ranson
Executive Chairman
BEng(ElecEng)

Dr. Christian Toouli
CEO & Managing Director
Btech Hons; PhD; GAICD

Dr. Bill Ketelbey
Executive Director
MBBCh; FFPM; MBA; GAICD

Iain Ross
Non-Executive Director
BSc Hons; CDir (IoD)

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

INDEPENDENT CLINICAL ADVISORY BOARD

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

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Chairman
GenesisCare · University of Sydney

Prof. John Simes AO
University of Sydney · NHMRC Clinical Trials Centre

Prof. Andrew McLachlan AM
University of Sydney · ANZAC Research Institute

Prof. John Zalcberg AO
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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Optimising Cancer Therapeutics for Patients

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USE OF FUNDS

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

Funding Letter of Support by Endpoints Capital

A follow-on/IPO capital raise is planned for Late 2025 / early 2026 following Investigational New Drug (IND) designations for the treatment of 1st-line mCRC and paediatric ependymoma.

Deflexifol® registrational trials planned in initiate in early 2026, with commercial launch planned for 2028.

New funding will support:

- Phase Ib/IIa **mCRC & paediatric brain cancer trials**.
- **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 late 2025 / early 2026**.

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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**
- Indicates superiority over standard 5-FU and LV formulations
- 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/m^2 bolus + 3000 mg/m^2 infusion

Stable Disease
5 months

Pancreatic Cancer
female, 75 years

Failed two prior lines
- FOLFIRINOX
- Gemcitabine/abraxane

Deflexifol™
525 mg/m^2 bolus + 3000 mg/m^2 infusion

Stable Disease
6 months

Metastatic colorectal cancer
male, 61 years

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

Deflexifol™
525 mg/m^2 bolus + 3800 mg/m^2 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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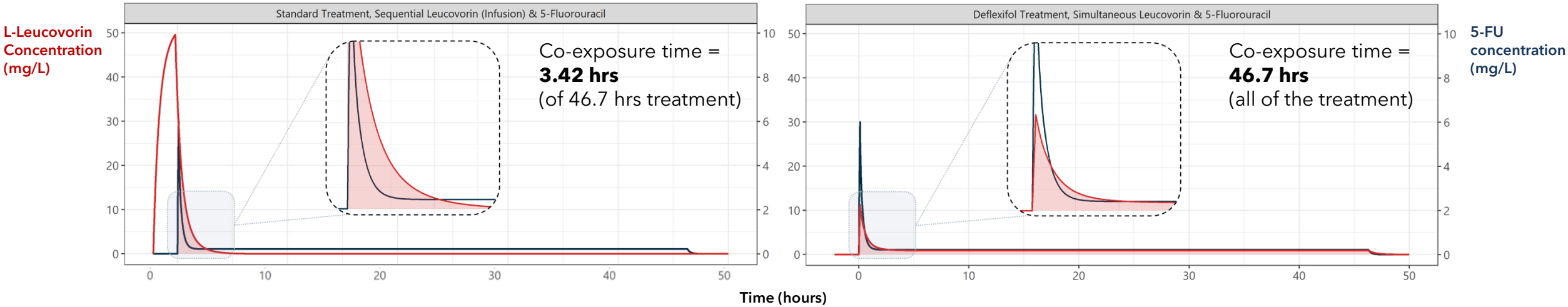
WHY DEFLEXIFOL™ ENHANCES EFFICACY

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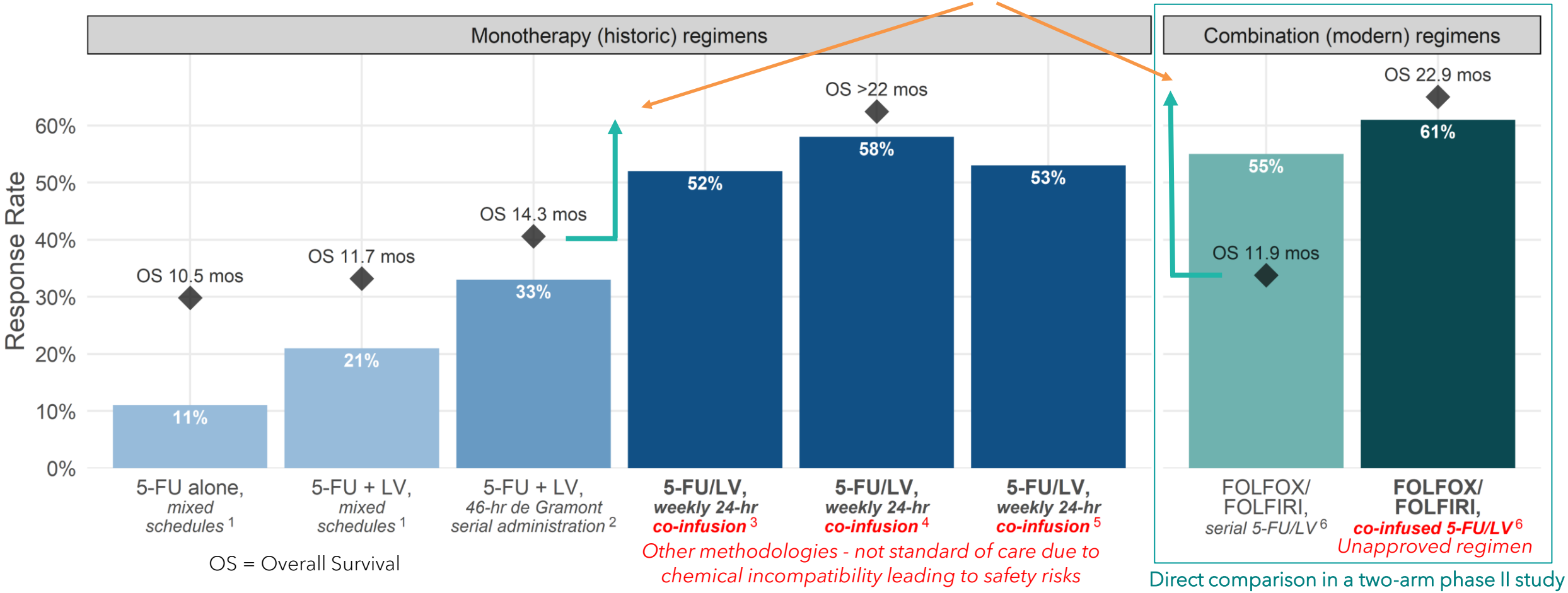
5-FU/LV CO-INFUSION IMPROVES ANTI-TUMOUR EFFICACY

- 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 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>

the children's hospital at Westmead
The Sydney children's Hospitals Network
Queensland Children's Hospital
Monash Children's Hospital
Women's and Children's Hospital ADELAIDE
ANZCHOG Australian & New Zealand Childrens Haematology/Oncology Group
KOALA KIDS ONCOLOGY AND LEUKAEMIA TRIALS
Perth Children's Hospital
The Royal Children's Hospital Melbourne
KIDS CANCER CENTRE SYDNEY CHILDREN'S HOSPITAL
zero CHILDHOOD CANCER
John Hunter Children's Hospital CHILDREN, YOUNG PEOPLE AND FAMILIES

[1] ACTRN12623000104651 (link)

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FP101B: HREC APPROVED PHASE 1B/2A TRIAL DESIGN (2024 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$^{\varnothing}$)

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$^{\varnothing}$)

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 mid-2024, pending successful capital raising
*ORR = Objective Response Rate; PFS = Progression Free Survival, MTD = Maximum Tolerated Dose, DLT = Dose Limiting Toxicity
$^{\varnothing}$ 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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REGISTRATION TRIAL: DRAFT PLAN FOR PHASE III TRIAL (Q4 2025)

1st line treatment of unresectable mCRC

- International, multi-centre registration trial (2025 – 2027)
- 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*

GLOBAL PHASE III TRIAL

A ~550 patient, blinded, randomized phase III study of Deflexifol™ in combination with oxaliplatin (DEFLOX) and bevacizumab vs mFOLFOX6 and bevacizumab in first-line unresectable metastatic colorectal cancer

↓

RANDOMIZATION 1:1

↓

DEFLOX + bevacizumab *i.v. 14-day cycle*	**mFOLFOX6 + bevacizumab** *i.v. 14-day cycle*

↓

Radiological response every 8 weeks (RECIST 1.1)

↓

Primary Objective: Best Objective Response Rate

Secondary Objectives: Progression Free Survival, Overall Survival, safety, Quality of Life

* 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 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:

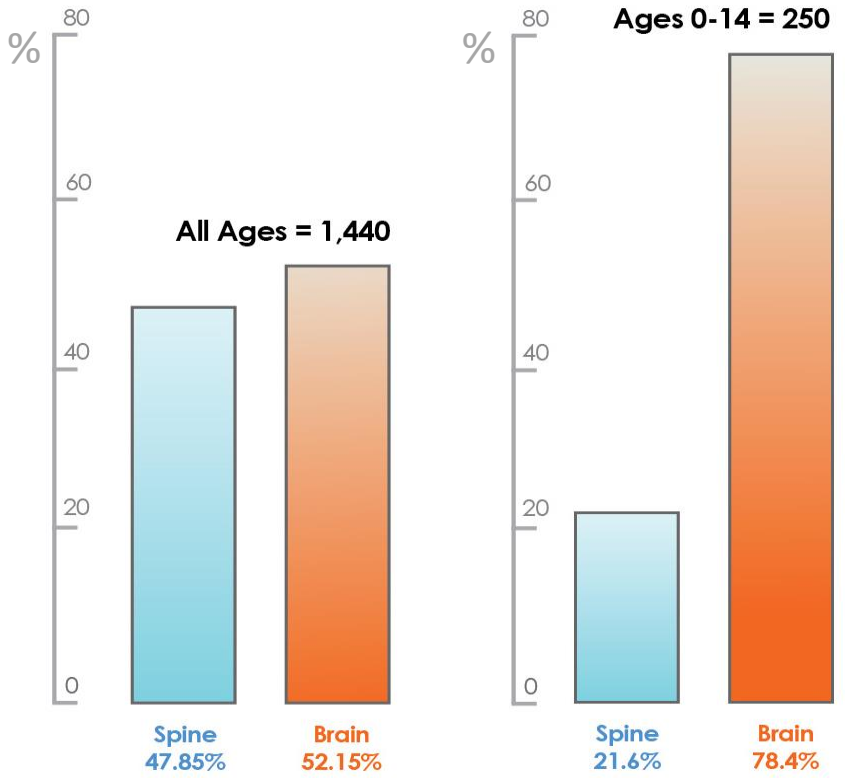
+2 yr exclusivity in EU, +1 yr exclusivity in South Korea

+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 Statustical 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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