FivepHusion

Corporate Presentation
November 2026

NEXT-GENERATION CANCER THERAPEUTICS

PRIORITISING CHILDHOOD BRAIN CANCER

Dr Christian Toouli, CEO & Managing Director
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NEXT-GENERATION STANDARD OF CARE

FivepHusion

Optimising 5-Fluorouracil (5-FU) clinical activity to generate superior treatment outcomes

5-FU (in various combinations)	• **A standard of care (SOC) for cancers with >8m patient incidence** • Colorectal (CRC), pancreatic, head & neck, gastric, breast etc.…
Sub-Optimal SOC	• **Poor inhibitor of thymidylate synthase** in the absence of its biomodulator leucovorin (LV) • **Continual exposure to LV is required,** but unachievable due to chemical incompatibility of current formulations • SOC "work-around" is sequential administration of 5-FU and LV with <10% co-exposure
Clinical Opportunity	• **Optimise 5-FU & LV to increase safety & efficacy** • **Exploit advantages to address unmet medical need cancers**
GLOBAL BLOCKBUSTER MARKET	• **Next generation backbone therapy for existing and new cancers**



STRATEGY: (1) Repurpose for fast-to-market paediatric ependymoma (First-In-Class Therapy; Orphan Indication)

(2) Partner for the larger market opportunity in mCRC (Best-In-Class)

Experienced Leadership & Strategic Partners

Established highly experienced Board, Management and Advisory Teams

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

Syneos Health · Pfizer CentreOne · allarity THERAPEUTICS · University of Wollongong Australia · Adelaide University · Monash University · Medicines Manufacturing Innovation Centre · FB Rice · The IP Navigators · Children's Cancer Institute

Independent Clinical Advisory Board

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



Prof. Stephen Clarke OAM
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
ICON · Monash University · All.Can

Paediatric Oncologist Principal Investigators



Prof. David Ziegler
zero Childhood Cancer · Kids Cancer Centre · Children's Cancer Institute · Sydney Children's Hospital Randwick



Dr Marion Mateos

DEFLEXIFOL®: FIRST-IN-CLASS & BEST-IN-CLASS

FivepHusion

A novel & optimised therapy

- **Superior co-formulation** of 5-fluorouracil **(5-FU)** & its biomodulator leucovorin **(LV)**
- **Continuous co-administration leading to maximal synergy**
- **Resulting in greater safety & superior efficacy**

Broad therapeutic utility & **market opportunities**

- Development priorities:
  1. **paediatric ependymoma (brain) cancer (FIRST-IN-CLASS)**
  2. **1st line metastatic colorectal cancer (mCRC) (BEST-IN-CLASS)**
- **Significant upside** potential in other 5-FU treated tumours
  - pancreatic, gastric, head & neck & breast (BEST-IN-CLASS)

Clinically advanced, technically & commercially low risk

- 3 phase I clinical studies successfully completed (Total N = 68)
  - ➢ **Greater safety, tolerability & efficacy**
- 5x independent surrogate phase II trials
  - ➢ **Greater response rate and survival in mCRC**
- Fast-tracked, low-risk 505(b)(2) regulatory pathway
- Low-cost, scalable manufacture with Pfizer
- **Peak sales estimate $1.8B** (conservative modelling in priority indications + some limited upside)
- Composition of matter IP + patent pipeline exclusivity to 2046

Phase II paediatric ependymoma trial initiating

Raising capital to prepare for pivotal trial

DEFLEXIFOL®

Combining and Optimising the Current Standard of Care

FivepHusion



5-fluorouracil (5-FU) + leucovorin (LV)
are the **backbone** of treatment for metastatic colorectal cancer and other gastrointestinal cancers

However, current formulations limit their safety and effectiveness

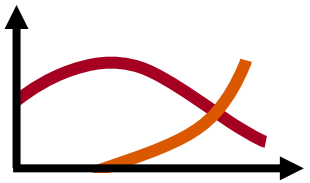
X The Problem with 5-FU + LV

5-FU + LV is synergistic, but chemically incompatible

- **Synergy:** LV enhances the efficacy of 5-FU
- **Chemically Incompatible**: Cannot be co-administered to maximise efficacy (crystallises and blocks the infusion line)

Sequential administration (current workaround) provides:

- **limited (<10%) co-exposure**
- **sub-optimal efficacy**



✓ The Solution: Deflexifol®

FivepHusion's Breakthrough: Deflexifol®

- **Deflexifol™ successfully combines 5-FU + LV**
- **Overcomes chemical incompatibility**
- **Increases co-exposure from <10% to 100%**
- **Delivers new highly valuable composition of matter IP**

↑ **Enhanced Efficacy**

↓ **Reduced Toxicity**

↑ **Higher Tolerated Dose**

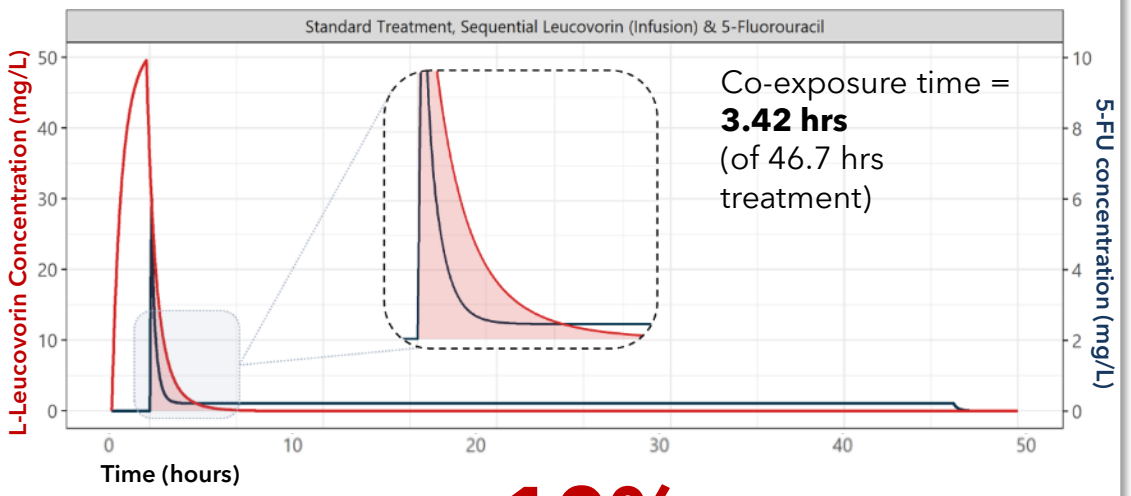
WHY DEFLEXIFOL® ENHANCES 5-FU EFFICACY

FivepHusion

Continual leucovorin exposure significantly enhances 5-FU anti-cancer potency[1,2]

Deflexifol® co-formulates 5-FU/LV safely with an FDA-approved cyclodextrin to enable maximal tumour co-exposure for optimal treatment efficacy

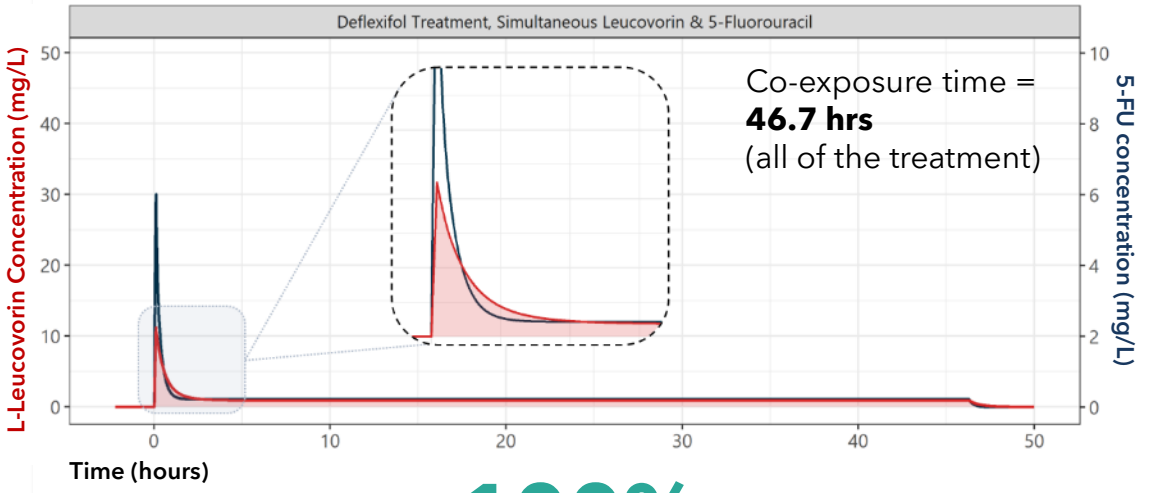
Current Standard of Care
Sub-Optimal Serial Administration



<10%

5-FU/LV co-exposure

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



100%

5-FU/LV co-exposure

Modelled pharmacokinetics based on published independent literature [3,4]

[1] Moran & Scanlon 1991, *Cancer Res* 51:4618; [2] Romanini *et al.* 1991, *Cancer Res* 51:789; [3] Maring et al. 2003, *Cancer Chemother Pharmacol.* 51:167; [4] Straw et al. 1984, *Cancer Res*. 44:3114

IMPROVED CLINICAL SAFETY AND EFFICACY

FivepHusion's two adult clinical trials demonstrated safety and efficacy signals

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

- **Reduced toxicity and improved tolerability**
- **Maximum tolerated dose 40% higher than SOC**, 525mg/m^2 bolus + 3400mg/m^2 infusion
- **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%
disease control rate

for regorafenib
(**US$580M** sales in 2023)

&

44%
disease control rate

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

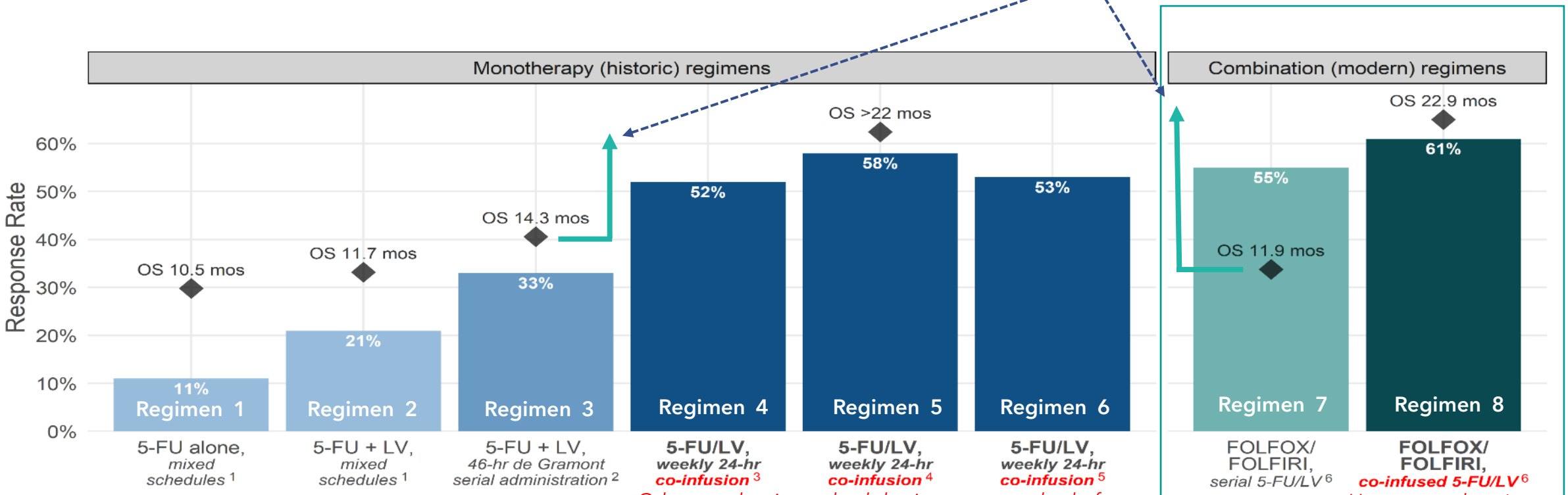
[1,2] Deflexifol® publications, conference proceedings and supportive literature can be found at: https://fivephusion.com/publications/
* Registration trial results: Regorafenib – PFS 1.9 (vs. 1.7 months placebo), OS 6.4 months (vs 5.0- months placebo); Lonsurf – PFS 2.0 months (vs. 1.7 months placebo), OS 7.1 months (vs. 5.3 months placebo). Grothey et al., 2013, Lancet, 381(9863):303; Mayer et al. 2015, N Engl J Med, 372(20):1909

5-FU/LV Co-Infusion Improves Anti-Tumour Efficacy

FivepHusion's thesis is supported by robust third-party data

- mCRC 1st line treatment has only incrementally improved over decades
- **Increasing 5-FU / LV co-exposure is associated with greater response and survival**
- **Independent phase II trials indicate superiority of 5-FU/LV co-infusion** (using unsafe / impractical/ unapproved methods).

Precedent for Deflexifol® - Designed to safely co-infuse 5-FU/LV to enhance efficacy



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

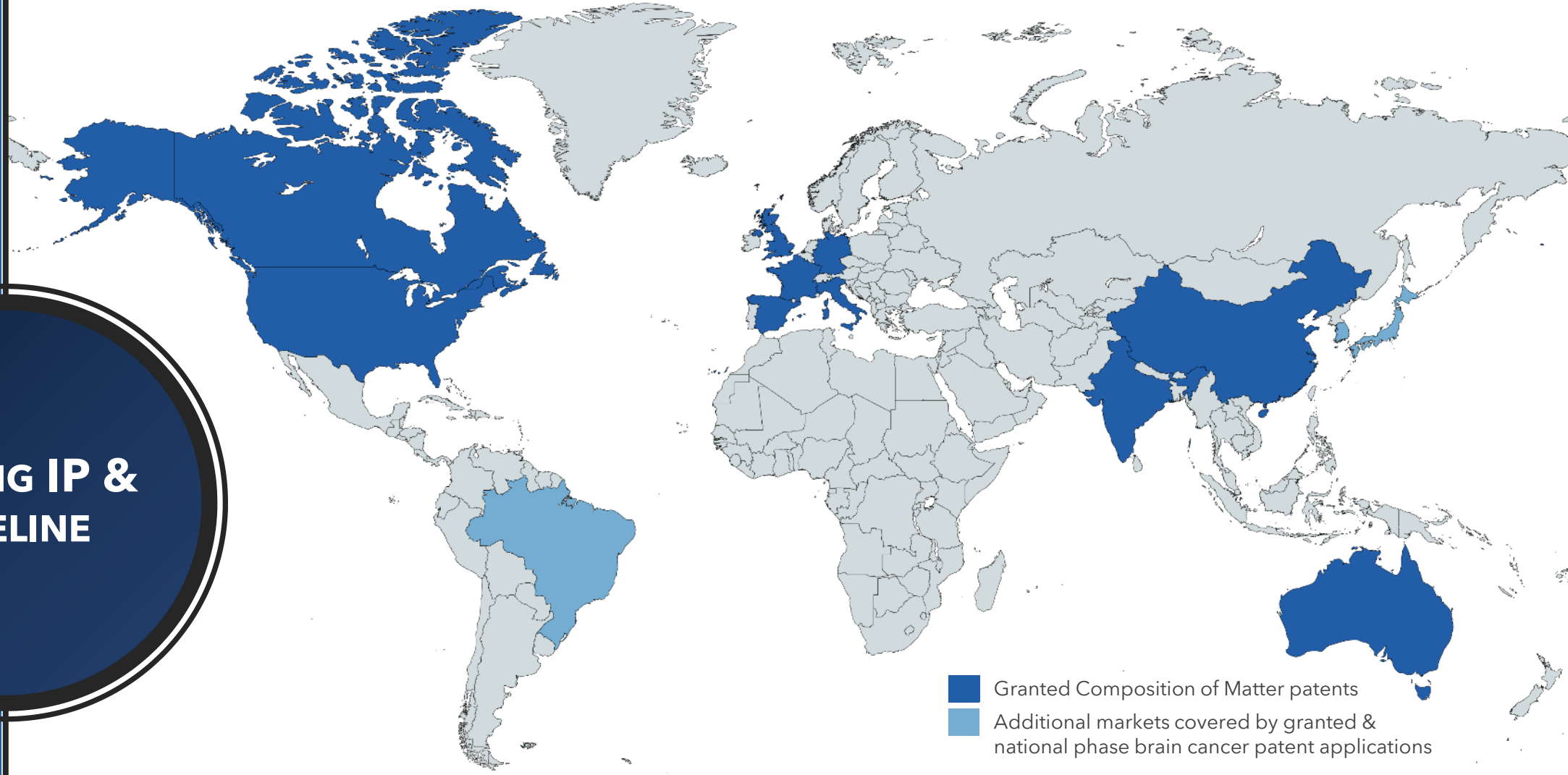
Direct comparison in a two-arm phase II study

OS = Overall Survival

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.

FOLFOX: 5-FU + LV + oxaliplatin
FOLFIRI: 5-FU + LV + irinotecan

Strong IP & Pipeline



- **Deflexifol® granted composition of matter formulation**
- **+ brain cancer patents** granted and at national phase prosecution
- **+ New composition** filed in 2026

expected exclusivity to

>2046

REPURPOSING 5-FU FOR PAEDIATRIC EPENDYMOMA

A leading drug candidate for an orphan indication with significant unmet medical need

PAEDIATRIC EPENDYMOMA

- **The third most common brain cancer in children**
- 4 per million incidence; peak <4 years of age
- ~50% patients survive 10 years after treatment[1]

CURRENT TREATMENT

- **No currently approved drug therapies**
- Surgical resection and adjuvant radiotherapy

5-FU RATIONALE

- **Promising pre-clinical and clinical data**[2,3,4]
- Sensitisation via frequent chromosome aberrations (1q+)[5]
- **Off-label compassionate use**[6]

ST JUDE 5-FU PHASE I TRIAL[4]

- **Promising 48% disease control rate** (5/23 PR and 6/23 SD)
  - Maximum *tolerated* dose: **400 mg/m² bolus dose**
  - Minimum *effective* dose: **500 mg/m² bolus dose**



[1] Marinoff et al., 2017, *J Neurooncol* 135:201-211; [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] Griesinger *et al.* 2024, *Clin Cancer Res.* 30(8):1544-54; [6] Anecdotal reports from leading paediatric oncologists practising in Australia, USA and EU;
PR = Partial Response; SD = Stable Disease

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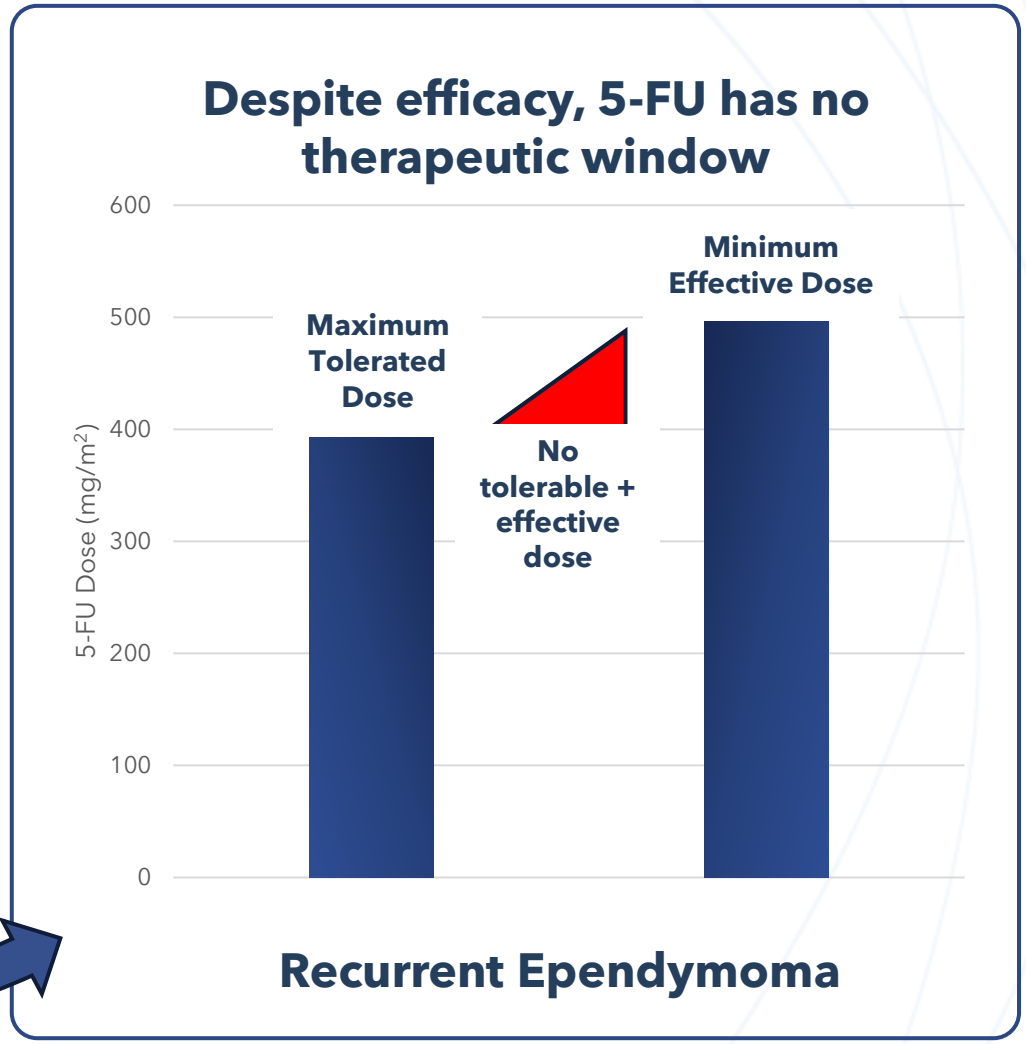
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DEFLEXIFOL®: FIRST FOR PAEDIATRIC EPENDYMOMA

Exploiting greater potency & improved safety & tolerability

FivepHusion

Phase I/II Deflexifol® at Relapse Trial (DART)

Phase I: Various brain cancers - SUCCESSFULLY COMPLETED

- N = 9: ependymoma (n=6), DMG (n=2) and ETMR (n=1)
- Safe and tolerable at significantly higher equivalent doses of 5-FU
- MTD - 525mg/m^2 bolus + 3000mg/m^2 infusion
  - **Deflexifol® MTD: ~9x St Jude phase 1 MTD**



* ACTRN12623000104651 (link); #SNO 2025 poster (link); DMG = Diffuse Midline Glioma; ETMR = Embryonal Tumor with Multilayered Rosettes; MTD = Maximum Tolerated Dose

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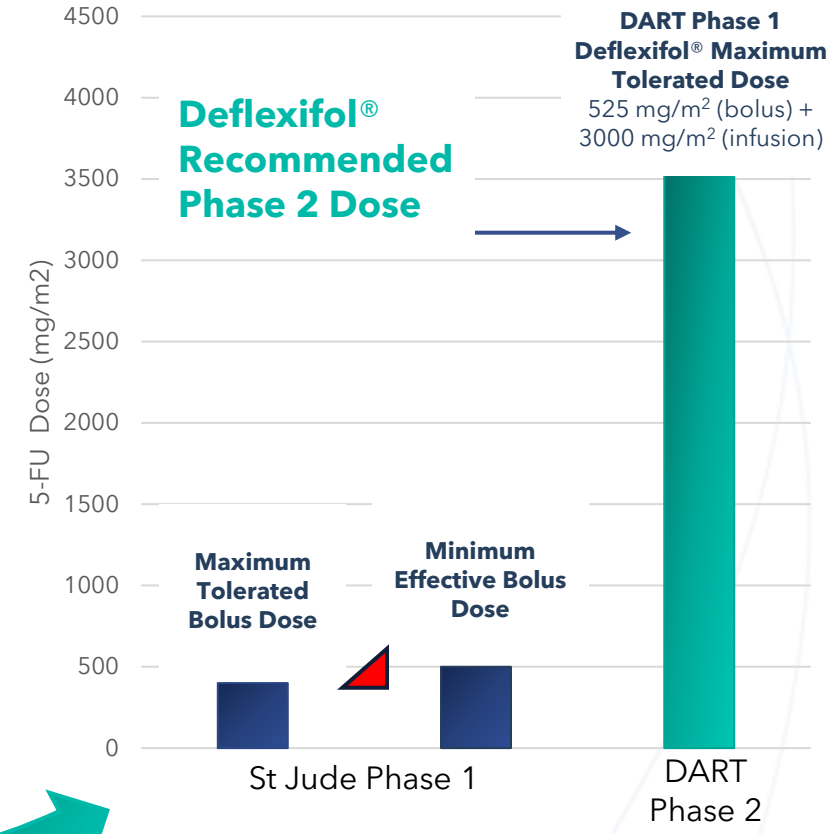
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  - **Deflexifol® MTD: ~9x St Jude phase 1 MTD**

Phase II: Recurrent or refractory ependymoma - INITIATED

- N = 10, 7 evaluable patients to be recruited (3 evaluable from Phase I)
- Response, survival and safety endpoints
- Eight clinical sites around Australia
- **Estimated top-line data H2 2027**

Investigating Deflexifol® at an expected safe, tolerable & efficacious dose



* ACTRN12623000104651 (link); #SNO 2025 poster (link); DMG = Diffuse Midline Glioma; ETMR = Embryonal Tumor with Multilayered Rosettes; MTD = Maximum Tolerated Dose

SIGNIFICANT COMMERCIAL OPPORTUNITIES

FivepHusion's conservative modelling indicates blockbuster status for Deflexifol®

Deflexifol® addresses global markets

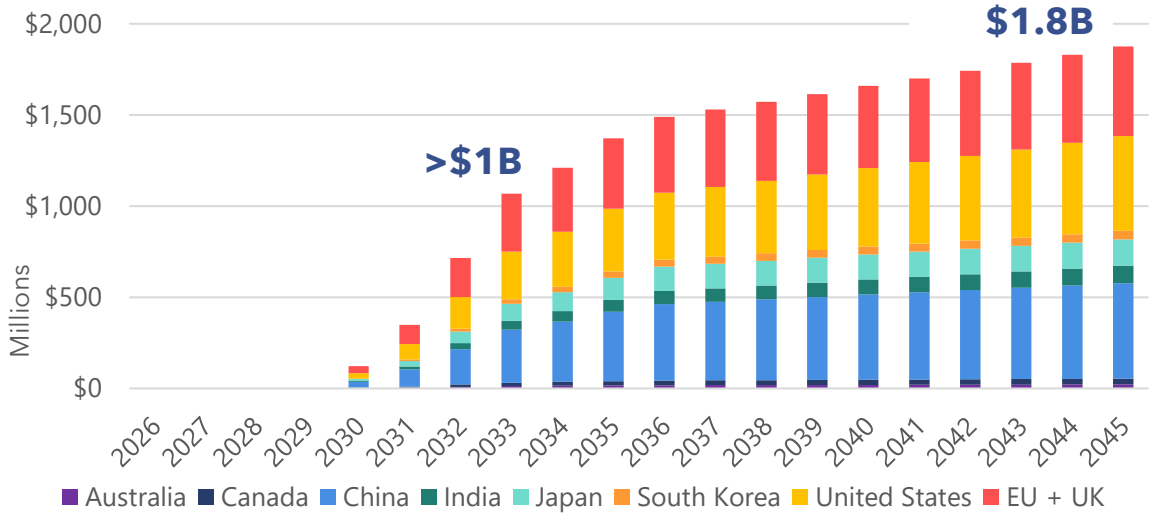
1. Paediatric ependymoma: **Part of the US$1.32B market**[1]

- **Fast path to approval & orphan premium pricing**

2. Metastatic colorectal cancer: ~500K patients p.a.[2]

- **US$13B** mCRC market[3], **majority receive 5-FU + LV**[4]
- FDA confirmed immediate **path to 1st line treatment**
- **Strong pharmacoeconomic value** / basis for **premium pricing**
- **Limited competition** – other drugs typically combine with 5-FU + LV

Deflexifol® Projected Sales[5]



Pipeline Upside:

+ Replace 5-FU+LV across solid tumour indications = **>8M patients**
+ **On mCRC approval:** Deflexifol® may also receive an **FDA registration label enabling** physician use **across all other solid tumour indications for which 5-FU + LV are currently utilised.**

Path to Substantial Value

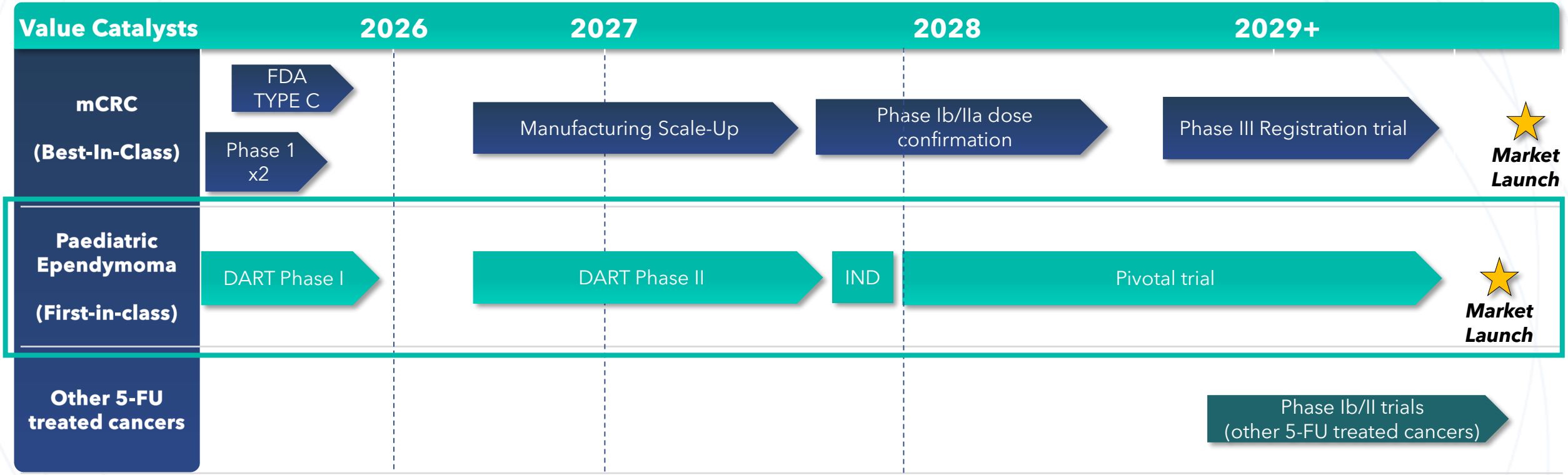
- **De-risked & accelerated regulatory pathways** to market
- Granted IP portfolio and pipeline **exclusivity to >2046**
- Commercial launch: As early as **2030**
- **Strong KOL** interest to switch to Deflexifol®

[1] Pediatric Brain Tumour Market – Market Research Future 2026
[2] Global Cancer Observatory 2020, Cancer Today; GLOBOCAN 2020
[3] 2025 Colorectal Cancer Market Insight, Epidemiology And Market Forecast - 2034
[4] Glimelius et al., 2021, *Cancer Treatment Reviews* 98:102218

[5] Indications: drug sales for the treatment of ependymoma, mCRC, CRC, breast, gastric, pancreatic

VALUE CREATION STRATEGY – ACCELERATE TO PIVOTAL TRIAL

FivepHusion



Licensing, partnering deals &/or acquisition

Recent deal precedents for paediatric brain cancer

Date	Type of Deal	Acquirer/Licensee	Target/Licensee	Stage	Upfront (US$)	Milestones (US$)	Total Deal Value (US$)
Jul-24	Ex-US license	IPSEN	Day One BIOPHARMACEUTICALS	Phase 3	$111m	$350m	**$461m**
Mar-25	Acquisition	Jazz Pharmaceuticals	CHIMERIX	Phase 3	$935m		**$935m**
Mar-26	Acquisition	SERVIER	Day One BIOPHARMACEUTICALS	Commercial	$2,500m		**$2,500m**

All development steps and timelines are indicative; IND = FDA Investigational New Drug Application


Millions of cancer patients are treated with chemotherapy unchanged since last century
FivepHusion is optimising treatment safety and efficacy, & unlocking multi-billion-dollar commercial opportunities

FivepHusion Key Highlights

FivepHusion's strategy presents a unique and compelling risk-reward profile

Multiple Blockbuster Markets	• **Paediatric ependymoma – Part of the US$1.32B paediatric brain cancer market -** rapid path to additional indications • **Metastatic colorectal cancer (mCRC)** ~500k patient incidence = **US$13B mCRC market** • **8.0m+ solid tumour diagnosed p.a**. (where 5-FU + LV are utilised)
Deflexifol® First-In-Class & Best-In-Class	• **Aiming to be the first approved therapy for paediatric ependymoma** • 5-FU + LV: Established standard of care' backbone therapy for mCRC (95% of patients). • **Aims to replace current 'standard of care' (SOC) backbone therapy**
Strong economics	• **Premium pricing** potential vs. generics, **driven by superior safety and efficacy** • **Rapid uptake** - KOLs believe **Deflexifol®** would be **widely adopted within 2 years** of clinical validation and launch • Conservative Modelling suggests **peak sales ~$1.8B+** (multiplies on higher pricing)
Clinically Validated	• 3 company clinical trials demonstrated **higher safety & tolerability** and **potent efficacy** • Current clinician 5-FU off-label use to treat ependymoma • 5 independent surrogate Phase II trials confirm rationale and superior co-infusion therapeutic mechanism
Fast-Tracked & Capital-Efficient	• Paediatric ependymoma – fast-tracked orphan indication; exploiting poor therapeutic window for 5-FU • **Active Phase II paediatric ependymoma** trial moving towards a pivotal trial • Fast-tracked development via 505(b)(2) pathway for 5-FU-treated cancers **enabling faster, lower cost approval** • Rare in oncology: **Deflexifol® is a 'next generation' superior co-formulation**
Significant Pipeline	• **Broader applications where 5-FU + LV are utilised**: pancreatic, gastric, breast, head & neck cancers
IP Protection	• **Granted Composition of Matter patents and pipeline**, expected **exclusivity to 2046**
Licensing Transactions	• Clear, short-term pathway to **regional and global licensing transaction opportunities with lucrative deal precedents**

EPENDYMOMA SENSITIVITY TO 5-FU

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

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



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

Supratentorial
~1/3 of childhood EPN [1]

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

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

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

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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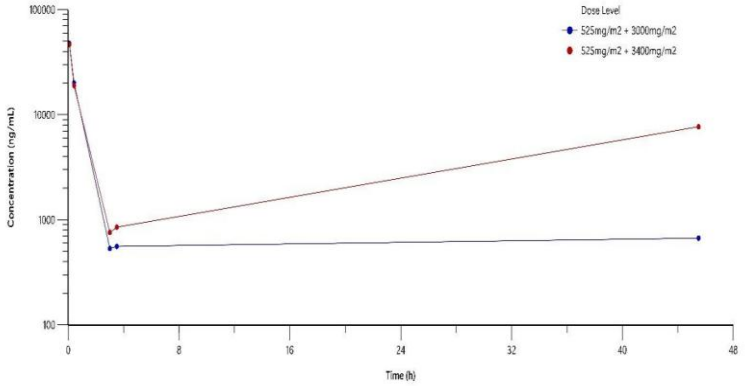
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Phase I/II Deflexifol® at Relapse Trial (DART)

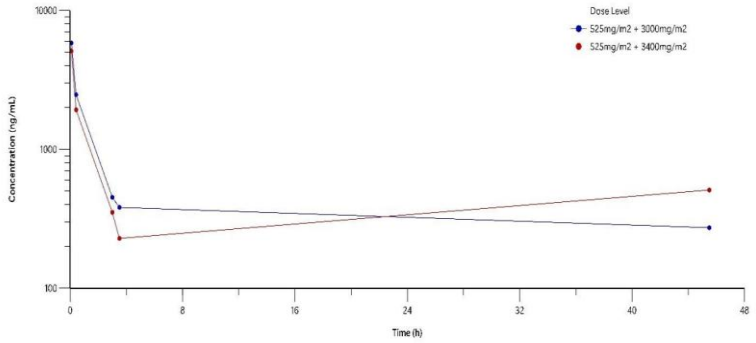
Phase I: Various Brain Cancers – Successfully Completed#

- N = 9: ependymoma (n=6), DMG (n=2) and ETMR (n=1)
- Patients infused over two days every two weeks
- MTD - 525mg/m^2 bolus + 3000mg/m^2 infusion
- Durable steady state 5-FU & LV over two-day infusion (100% co-exposure)

5-FU

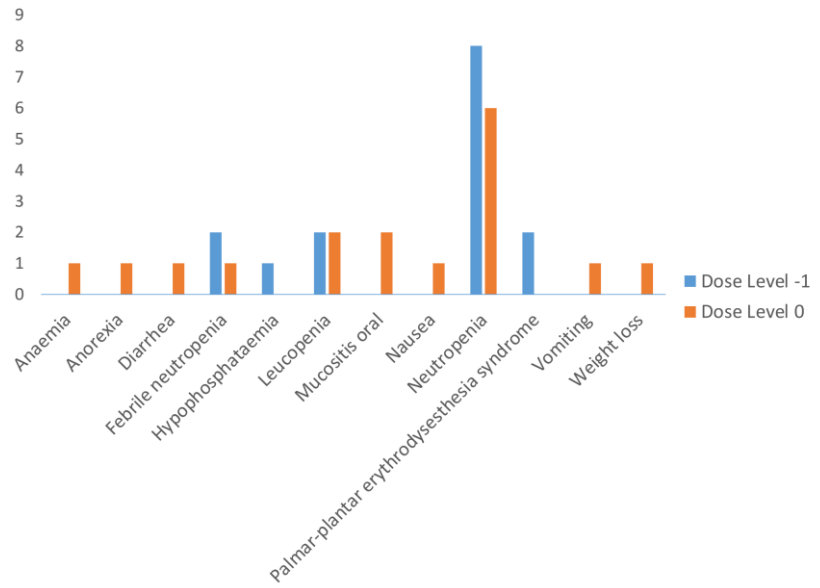


(s)-Leucovorin



PK analysis of 5-FU and (s)-Leucovorin (active enantiomer) on Day 1of Deflexifol® administration. Timepoints: pre-bolus, post bolus, pre-infusion, 2.5 hours post infusion, 3 hours and 45 hours post infusion/

Deflexifol® was well tolerated with treatment related AEs (non-DLTs) similar to 5-FU



Grade 3/4 AEs. Definite, probable or possible causality to Deflexifol®, stratified by dose level assigned.
Y-axis: Number of events per AE
No participants discontinued treatment due to toxicity.

ACTRN12623000104651 (link); #SNO 2025 poster (link); DMG = Diffuse Midline Glioma; ETMR = Embryonal Tumor with Multilayered Rosettes; # High level PK, safety and MTD data presented at SNO 2025
AE: Adverse Event; DLT: Dose Limiting Toxicity.

5-FU/LV Co-administration: Precedents & Comparison

FivepHusion

Deflexifol® is the only co-infusion strategy that is clinically and commercially viable

Two separate pumps[1]	Dilution strategies[2-3]	Sodium salt LV[4-5]	Deflexifol®
✓ Considerably improved survival & response rate in untreated & previously treated mCRC patients.[1]	✓ Considerably improved response rates in untreated & previously treated mCRC patients.[2,3]	✓ Significantly improved patient survival in 1st line mCRC when used in modern infusion regimens.[4,5]	✓ **No precipitation** or catheter blockages.
× **Not clinically or commercially feasible** - requires two pumps & intravenous lines.	× **Does not prevent precipitation** and catheter blockages.	× **Not approved** for this usage.	✓ Pain-free, **physiological-pH** formulation.
	× **Not approved** for this usage.	× **Requires alkaline pH of 9.0.**	✓ Highly tolerable, with a **higher MTD than 5-FU.**
		× **Similar toxicity to standard dose administration.**	✓ **Improved safety.**
			✓ **Demonstrable efficacy** in end-stage patients following previous 5-FU failure.
			✓ **Composition of matter patent protection.**

While surrogate studies provide supporting evidence, they remain commercially unviable and impractical in real-world use – **positioning Deflexifol® as the only path forward with both safety and efficacy.**

[1] Ardalan *et al.*, 1991, J Clin Oncol. 9:625.
[2] Yeh *et al.* 1997, Anticancer Res. 17:3867.
[3] Yang *et al.* 1999, Cancer 85:1925.
[4] Bleiberg *et al.* 2012, Acta Gastroenterol Belg. 75:14.
[5] Romano *et al.* 2021, Oncotarget 12:221.

DEFLEXIFOL® CASE STUDIES

Efficacious after 5-FU + LV failure in end-stage adult cancer patients

FivepHusion

Heavily pre-treated patients **experienced benefit** from optimised 5-FU/LV delivery

Activity after failure of 5-FU treatment - **Indicates Deflexifol® superior anti-cancer potency**

Phase Ib/IIa trial^ Demonstrated

Disease control:
9/13 (69%) evaluable patients

Median progression free survival:
28.2 weeks

Metastatic Colorectal Cancer

Patient: male, 59 years

Failed two lines previously:

- FOLFOX
- FOLFIRI + bevacizumab

Treatment: Deflexifol®

- 525 mg/m^2 bolus + 3000 mg/m^2 infusion

Result: Stable Disease 5 months

Pancreatic Cancer

Patient: female, 75 years

Failed two lines previously:

- FOLFIRINOX
- Gemcitabine/Abraxane

Treatment: Deflexifol®

- 525 mg/m^2 bolus + 3000 mg/m^2 infusion

Result: Stable Disease 6 months

Metastatic Colorectal Cancer

Patient: male, 61 years

Failed four lines previously:

- FOLFOX + bevacizumab
- FOLFIRI
- Panitumumab
- Lonsurf®

Treatment: Deflexifol®

- 525 mg/m^2 bolus + 3800 mg/m^2 infusion

Result: 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 = tumour reduced in size by ≥30%

New Version Pricing Premiums

Deflexifol® has blockbuster potential at all potential pricing outcomes

New version drugs commanded between 2-175x price premiums in comparison to the originator drugs

- Most of these assets demonstrated only modest or even non-inferior improvements in safety and/or efficacy
- Isofol Medical **expected >US$4,000**/month for arfolitixorin (new version of LV) = **8x increase over LV** [1]
  - Analysts expected $3,000 – $6,600/month prior to clinical failure [2, 3]

5-FU & LV: Current Pricing ($US)	
5-FU + LV: Per month	~$180 – $800
5-FU + LV: Per course*	~$1,500 – $6,500

Deflexifol®: Potential Pricing		
Low Case (~2x)	~$1,100/month;	~$9,000/course
Mid Case (~8x)	~$4,400/month;	~$35,000/course
Courses/patient	~2-3x	
Cost/patient	**$18,000 → $70,000**	
COGS	Immaterial	
Cases/annum	Ependymoma = ~2000 mCRC = ~500,000 Other Solid Tumours = 8,000,000+	

Originator	New Drug	Region	Originator Price	New Drug Price	Price Increase
5-FU/LV	**Xeloda® (capecitabine)**	US	~$185/month	~$5,900/month	**32x**
LV calcium (folinic acid)	**Fusilev® (levo-LV)**	US	~$55/dose	~$1,500/dose	**27x**
Daunorubicin + cytarabine Price is for 2x induction cycles + 2x consolidation cycles	**Vyxeos®**	US	~$5,200	~$128,000	**24x**
		UK	~£6,886	~£82,458	**12x**
		Germany	~€2,163	~€132,056	**61x**
		Italy	~€535	~€84,474	**158x**
		Spain	~€534	~€93,600	**175x**
Paclitaxel (Taxol)	**Abraxane® (nab-paclitaxel)**	US	$150/dose generic; $1,000/dose branded	$4,200 /dose	**4-42x**
		UK	£668/3wks	£1,230/3wks	**2x**
Paclitaxel (Taxol)	**Taxotere® (docetaxel)**	US	$150 /dose generic; $1,000/dose branded	$2,500/dose	**2.5-17x**
		UK	£668/3wks	£1,232/3wks	**2x**
Doxorubicin (Adriamycin)	**Doxil® (Doxorubicin liposomal)**	US	$1,066/month	$2,311/month	**2x**
Cytarabine	**DepoCyt® (Cytarabine liposomal)**	US	$84/month	$4,762/month	**57x**

[1] Isofol Medical AB, IPO Prospectus 2017; Isofol Medical, Arfolitixorin overview, 2020
[2] DNB Markets, Isofol Medical Equity Research 15 Nov 2020; Redeye research update Isofol Medical, 15 Nov 2020
[3] Wolters Kluwer Medi-Span Price Rx Accessed May 2020
* An average course of treatment is 8 months
Pricing data sourced from published literature and national pricing & reimbursement authorities (e.g. CMS, G-BA, NICE, AIFA, etc). Prices differ across geographic regions and are subject to change over time due to changes in legislation, demand, shortages, and other factors, thus prices listed on this slide may be subject to change in the future.

FDA Confirmed Path To Market for mCRC

Feedback on FivepHusion data set, clinical development, CMC and mCRC regulatory plans for Deflexifol®

Key FDA Feedback

1. **Deflexifol® can be immediately developed for 1st line mCRC patients**
   - **No need for phase II** due to approved drugs with established safety and tolerability
   - **No need to first seek registration in later lines of therapy**
2. **Advice on design of planned phase Ib/IIa ("combo") trial confirming Deflexifol® dose in FOLFOX** – i.e., when combined with oxaliplatin & bevacizumab
   (*Trial is HREC approved and ready to initiate*)
3. **Only one successfully conducted phase III** pivotal trial required to support registration
4. **Accelerated regulatory path** for registration in mCRC (FDA 505(b)(2))

Endorses our plan to accelerate towards phase III development and registration for Deflexifol®

*FDA Type C meeting feedback received H1 2023. Press release can be found here: Link

mCRC: HREC Approved Phase Ib/IIa Trial Design Study^

FivepHusion

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

Trial Design

- **1st line unresectable mCRC**
- **Two stage phase Ib/IIa** Trial Design
  - **40 – 50 patients**; trial duration **~12 months**

Endpoints

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

PART A

Dose Escalation Cohorts (3 + 3)

(9 – 18 pts, 3 trial sites; ~6 - 8 months∅)

Standard of Care

OXALIPLATIN
85 mg/m²

BEVACIZUMAB
5 mg/kg

⊕ **DEFLEXIFOL® BOLUS#**
400 mg/m²

⊕ **DEFLEXIFOL® INFUSIONΩ**

Dose: → **2400 mg/m²**

No DLTs ↑

3000 mg/m²

No DLTs ↑

3400 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. Trial planned to commence H2 2027, 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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