



Investor Presentation  
April 2026

# **NEXT-GENERATION CANCER THERAPEUTICS**

***DE-RISKED DRUG DEVELOPMENT OPPORTUNITIES  
TARGETING GLOBAL MARKETS***

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**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**

Optimising the standard of care, backbone of cancer treatment

## Deflexifol<sup>®</sup>: A next-generation, best-in-class treatment

### A new & optimised standard of care therapy

- Superior co-formulation of **5-fluorouracil (5-FU)** & its biomodulator **leucovorin (LV)**
- Positioned to **replace standard therapy** in solid tumours
- Sales revenue potential **≥US\$1B**

### Broad therapeutic utility & market opportunities

- Priority development indications:
  - **paediatric ependymoma (brain) cancer**
  - **1<sup>st</sup> line metastatic colorectal cancer**
- **Significant upside** potential in other solid tumours
  - pancreatic, gastric, breast, head & neck cancers

### Technically low-risk & clinically advanced

- **3 clinical studies** successfully completed
- **5x surrogate pII trials** support increased survival benefit
- **Fast-tracked, low-risk 505(b)(2) regulatory pathway**
- **Low-cost, scalable manufacture with Pfizer** in Melbourne
- **Endorsed by leading oncologists**
- **Granted composition of matter IP** + patent pipeline
- Invited to submit a **\$5M non-dilutive** Industry Growth Partnership grant proposal

**Capital raising to position FivepHusion to reach a registration trial with strong partnering appeal**

# EXPERIENCED LEADERSHIP & STRATEGIC PARTNERS

Established highly experienced Board, Management and Advisory Teams

## Board



**David Ranson**  
Executive Chairman  
BEng(ElecEng)



**Dr. Christian Touli**  
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



## 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  
 



**Prof. John Simes**  
AO  
 



**Prof. Andrew McLachlan**  
AM  
 



**Prof. John Zalcborg**  
AO  
  

## Founder Advisory Board

Inventors of Deflexifol® contributing expertise to ongoing development



**Prof. Philip Clingan**  
OAM



**Senior Prof. Marie Ranson**



**Emeritus Prof. John Bremner**  
AM

# MULTIPLE BLOCKBUSTER OPPORTUNITIES

Deflexifol® & pipeline opportunity ResectAssist™ have broad applications in solid tumours

## Deflexifol®

### Paediatric Ependymoma

#### Entering Phase II

Primary endpoint: Efficacy (response rate)  
Secondary Endpoints: Survival

#### Thesis

Deflexifol® to become the first approved therapy

#### Orphan Disease

**3<sup>rd</sup> Most Common**  
**Brain cancer in children**

**23 - 45%**  
**5-year progression-free<sup>3</sup>**

### Metastatic Colorectal Cancer

#### Entering Phase Ib/IIa

Primary endpoints: safety & maximum tolerated dose  
Secondary Endpoints: Efficacy

#### Thesis

Deflexifol® to replace backbone 1<sup>st</sup> line therapy: 5-FU & LV

#### Blockbuster Global Market

**1.9m**  
**cases per annum**  
(20-30% metastatic<sup>1</sup>)

**930k**  
**deaths per annum<sup>2</sup>**

### Potential Indications

Pancreatic Cancer  
Gastric Cancers  
Breast Cancer  
Head & Neck Cancers

#### Thesis

Optimise treatment across other 5-FU & LV indicated solid tumours.

**All present**  
**Blockbuster**  
**Markets**

## ResectAssist™

### Solid Tumours

#### Initial Focus

**Downstaging pancreatic cancer tumours** to resectable with curative intent

#### Thesis

A novel drug delivery technology platform:  
facilitating intra-tumoral delivery of approved (FOLFIRINOX) and innovative drugs

**Lead indication:**  
**Pancreatic Cancer**  
**>\$7.0B**  
**market opportunity<sup>4</sup>**

1. Global Cancer Observatory 2020, Cancer Today; GLOBOCAN 2020  
2. <https://www.who.int/news-room/fact-sheets/detail/colorectal-cancer>

3. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10036929/>  
4. Polaris Market Research 2022 - pancreatic cancer market in 2030

## Combining and Optimising the Current Standard of Care



# Metastatic colorectal cancer (mCRC)

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<sup>1</sup>

X

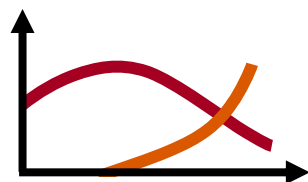
## The Problem with 5-FU + LV

**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 co-exposure and**
- **sub-optimal efficacy**



✓

## The Solution: Deflexifol®

**FivepHusion's Breakthrough: Deflexifol®**

- **Deflexifol® successfully combines 5-FU + LV**
- **Overcomes chemical incompatibility**
- **Increases co-exposure from 3 hours → 47 hours**
- **Delivers new highly valuable composition of matter IP**



**Enhanced  
Efficacy**



**Reduced  
Toxicity**



**Higher  
Tolerated Dose**

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

# CONFIRMED IMPROVED SAFETY AND EFFICACY

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

FivepHusion has treated **59 adult end-stage patients** with a **variety of solid tumours demonstrating**<sup>1</sup>

- 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**<sup>2</sup> demonstrating improved anti-tumour activity and significant survival benefits

## Deflexifol<sup>®</sup> 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

&

**44%**  
disease control  
rate

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

for Lonsurf<sup>®</sup>  
(**US\$550M** sales in 2023)

<sup>1,2</sup> Deflexifol<sup>®</sup> publications, conference proceedings and supportive literature can be found at: <https://fivephusion.com/publications/>

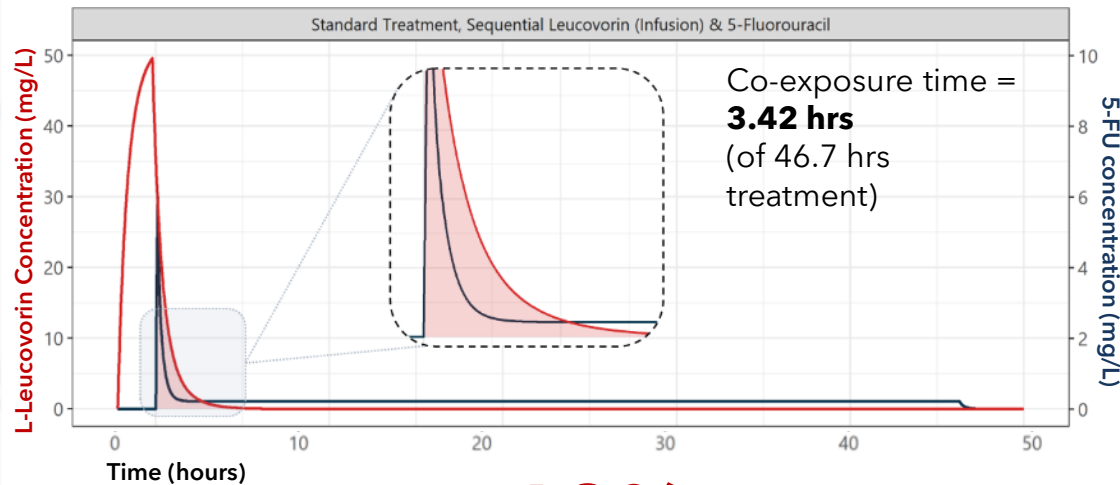
\* Registration trial results: Regorafenib - PFS 1.9 (vs. 1.7 months placebo), OS 6.4 months (vs 5.0- months placebo); Lonsurf - PFS 2.0 months (vs. 1.7 months placebo), OS 7.1 months (vs. 5.3 months placebo). Grothey et al., 2013, Lancet, 381(9863):303; Mayer et al. 2015, N Engl J Med, 372(20):1909

# WHY DEFLEXIFOL® ENHANCES EFFICACY

Deflexifol® increases co-exposure from 3.4 hours to 46.7 hours

Deflexifol® co-formulates 5-FU/LV safely with an 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

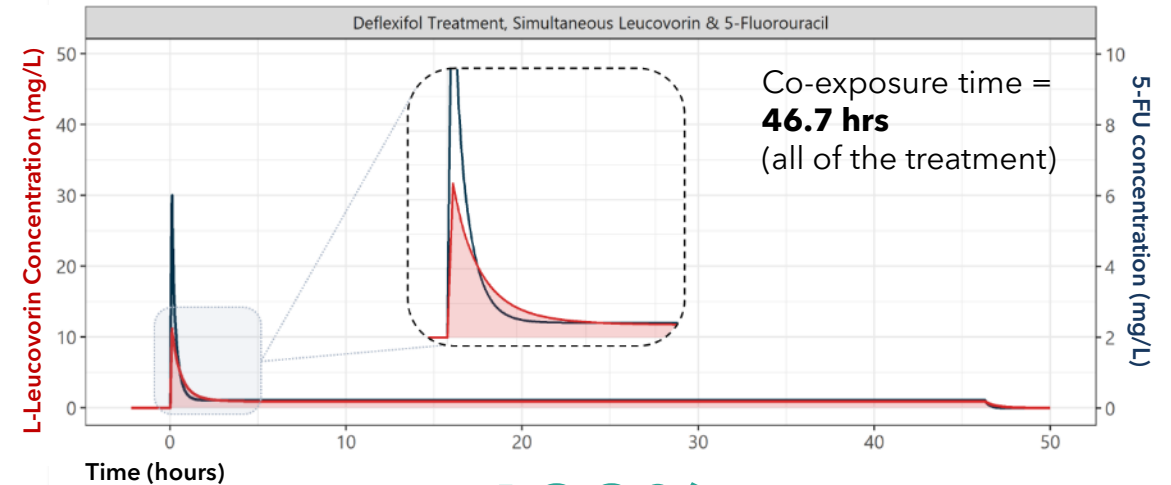
## Current Standard of Care Sub-Optimal Serial Administration



**<10%**

5-FU/LV co-exposure

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



**100%**

5-FU/LV co-exposure

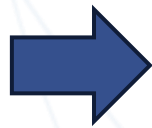
# 5-FU/LV CO-INFUSION IMPROVES ANTI-TUMOUR EFFICACY & SURVIVAL

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

- **Five independent surrogate mCRC clinical studies**<sup>(1-5)</sup> demonstrate that simultaneous 5-FU & LV delivery achieves superior response rates and survival (*using unapproved and/or unsafe methods that may block infusion lines*)
- **Two comparative trials demonstrate a survival benefit of simultaneous 5-FU & LV** administered as part of current Standard of Care mCRC regimens:
  - FOLFOX = 5-FU + LV + oxaliplatin
  - FOLFIRI = 5-FU + LV + irinotecan)

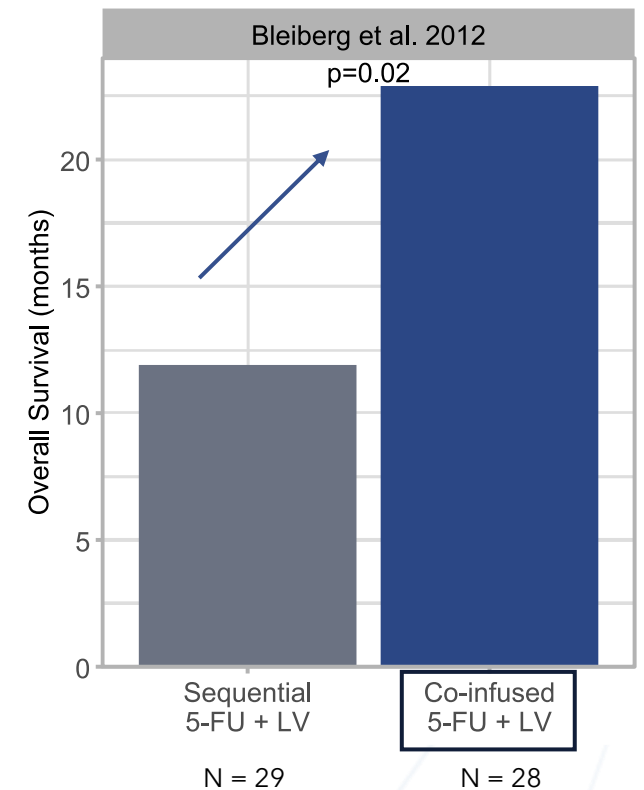
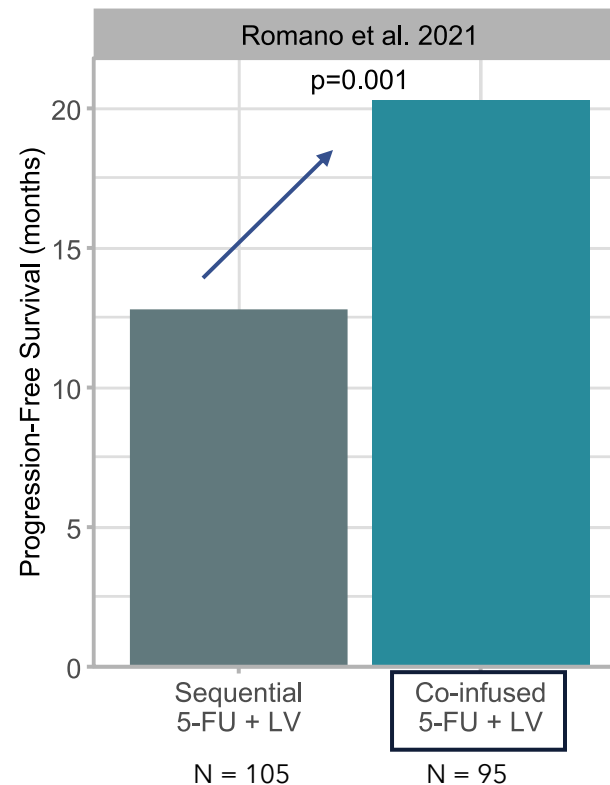
Reported:

- **Near doubling** in duration of patient survival
- **~40-60% reduction** in rate of progression or death



**De-risks and justifies Deflexifol<sup>®</sup> development & commercialisation**

## PRECEDENT CO-INFUSION COMPARATIVE STUDIES WITH FOLFOX/FOLFIRI



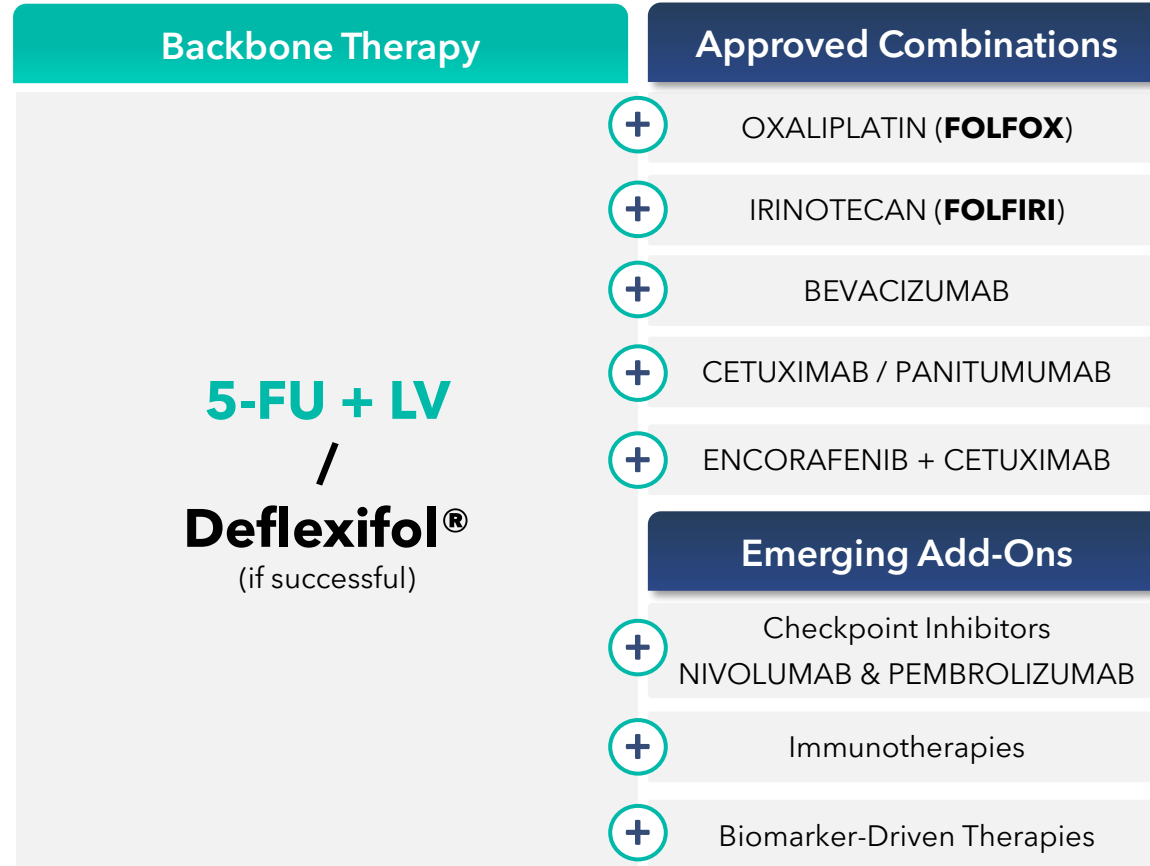
1. Ardalan et al. 1991, *J Clin Oncol.*, 9(4):625-30.  
2. Yeh et al. 1997, *Anticancer Res.*, 17(5B):3867-71.

3. Yang et al. 1999, *Cancer*, 85(9):1925-30.  
4. Bleiberg et al. 2012, *Acta Gastroenterol Belg.*, 75(1):14-21.

5. Romano et al., 2021 *Oncotarget* 12(3):221

# DEFLEXIFOL® A NEW BACKBONE THERAPY

Deflexifol® aims to replace 5-FU + LV as the backbone therapy of mCRC



5-FU & LV (Deflexifol®) faces limited competition risk as it will likely remain as a Backbone Therapy with new mCRC treatments utilised in combination.

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

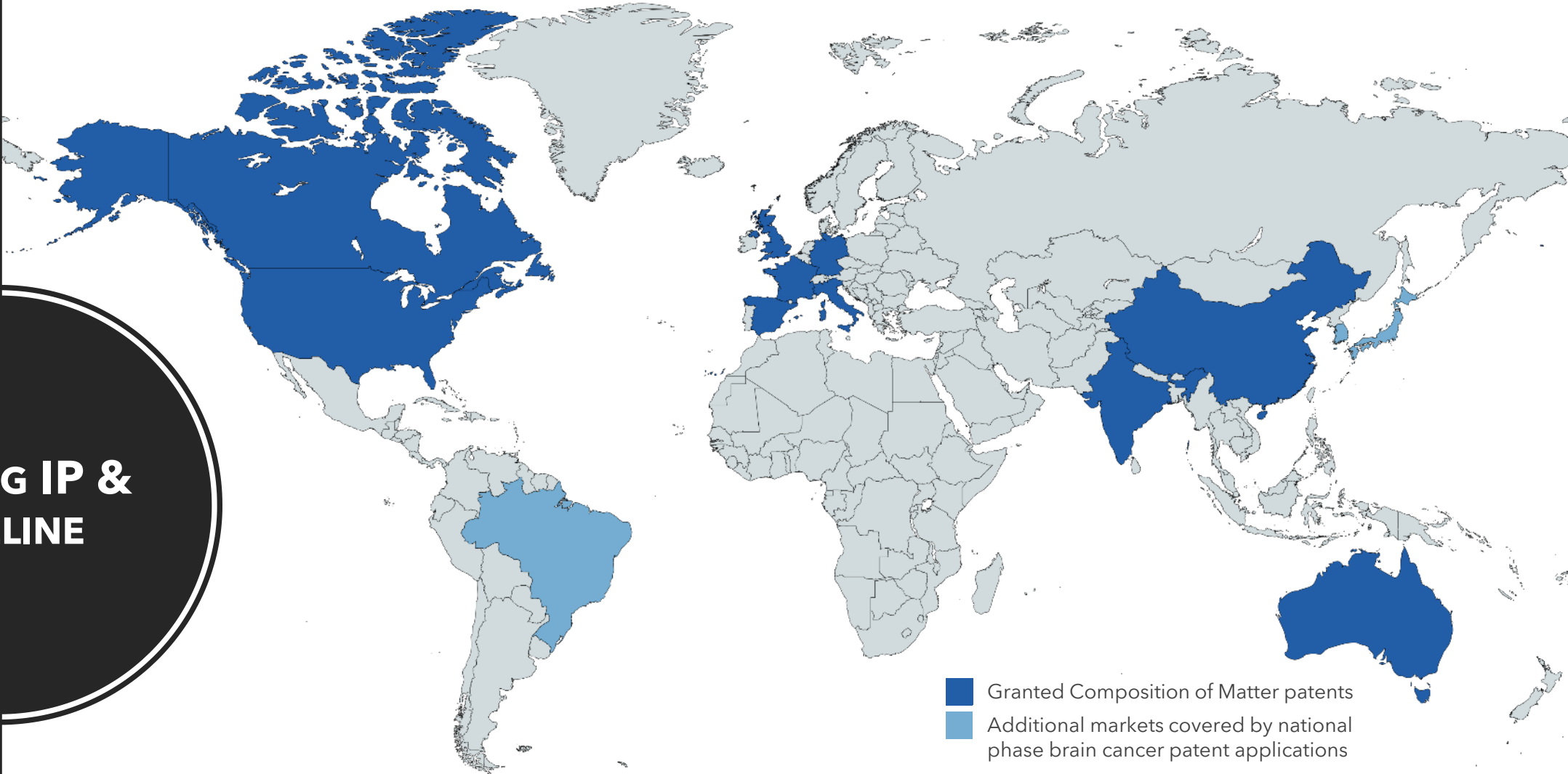
## Key FDA Feedback

- 1. Deflexifol® can be immediately developed for 1<sup>st</sup> 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®**

# STRONG IP & PIPELINE



- **Granted composition of matter**
- Patents in prosecution
- **New composition** filed in 2025
- IP pipeline 2026

expected  
exclusivity to  
**>2045**

# DEFLEXIFOL®: PAEDIATRIC EPENDYMOMA

Strategic Path to Market - Aiming to be the first approved drug for this cancer

## 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<sup>1</sup>: 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**

<sup>1</sup>Wright et al. 2015, *Neuro Oncol.*, 17(12):1620-27

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

Ongoing national investigator-led trial

## Trial Outcomes So Far

### Part A: **SUCCESSFULLY COMPLETED**

- 9 patients treated
- **Safe & tolerable dose (525mg/m<sup>2</sup> bolus + 3000mg/m<sup>2</sup> infusion)**  
(**25% higher** than 5-FU maximum tolerated dose in adults)
- Data presented at Society of Neuro-Oncology (November 2025)

### Part B: Phase II in recurrent ependymoma patients

- 7 evaluable patients to be recruited (3 evaluable from Part A)
- Patient recruitment commencing in Q2 2026



# SIGNIFICANT COMMERCIAL OPPORTUNITIES

FivepHusion's conservative modelling indicates blockbuster status for Deflexifol®

## Deflexifol® addresses global markets

**Global annual colorectal cancer incidence: 1.9M**

- **20-30%** diagnosed metastatic<sup>1</sup>
  - **380K - 570K new cases are metastatic (mCRC)**
- **~50% of patients with earlier-stage CRC** will eventually develop metastases<sup>2</sup>
- **US\$13B** mCRC market<sup>3</sup>, **majority receive 5-FU + LV**<sup>4</sup>
- FDA confirmed immediate **path to 1<sup>st</sup> line treatment**
- **Strong pharmacoeconomic value** / basis for **premium pricing**
- **Limited competition** - other drugs typically combine with 5-FU + LV

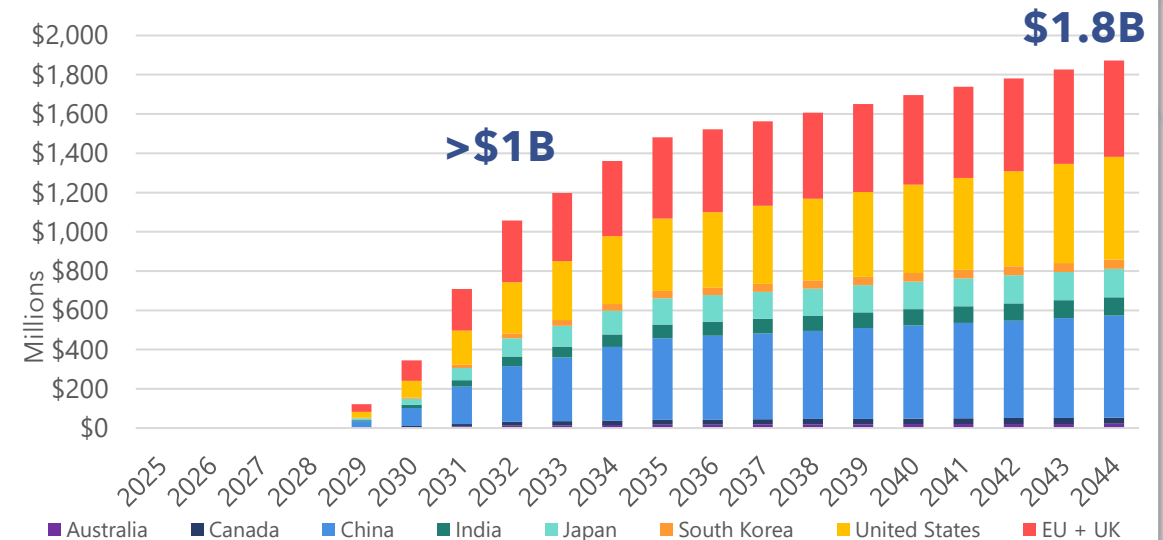
## Pipeline Upside:

- + Paediatric brain cancer: **US\$1.84B**<sup>5</sup> → Adult brain cancer
- + 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.**

## Deflexifol® Projected Sales<sup>6</sup>



## Path to Substantial Value

- **De-risked & accelerated regulatory pathways** to market
- Commercial launch: As early as **2029**
- **Strong KOL** interest to switch to a superior co-formulation
- Projected global peak sales: **US\$1.8B**

<sup>1</sup> Global Cancer Observatory 2020, Cancer Today; GLOBOCAN 2020

<sup>2</sup> Metastatic colorectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up †  
Van Cutsem, E. et al. Annals of Oncology, Volume 25, iii1 - iii9

<sup>3</sup> 2025 Colorectal Cancer Market Insight, Epidemiology And Market Forecast - 2034

<sup>4</sup> Glimelius et al., 2021, Cancer Treatment Reviews 98:102218

<sup>5</sup> Market Research Future 2023

<sup>6</sup> Indications: drug sales for the treatment of mCRC, ependymoma, CRC, breast, gastric, pancreatic

# RESECTASSIST™: BIODEGRADABLE DRUG-ELUTING IMPLANT

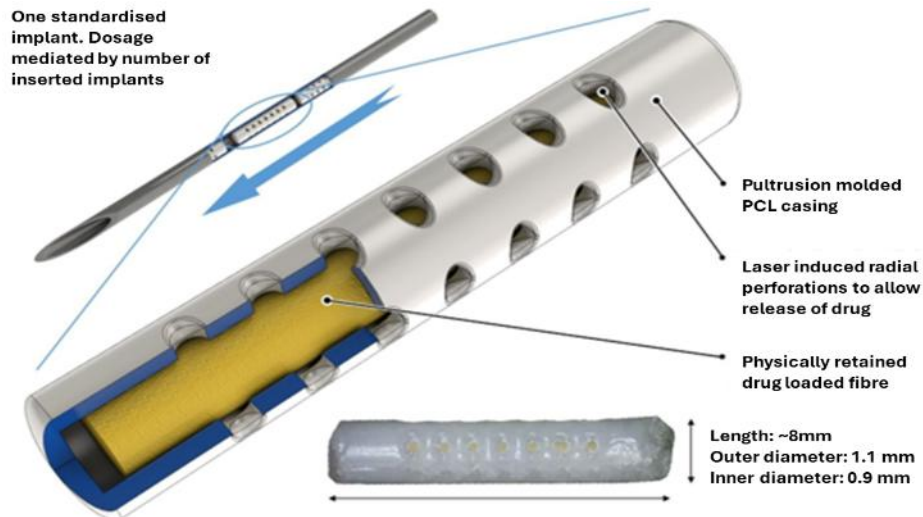
Exclusive option over ResectAssist™ significantly bolsters FivepHusion's pipeline

## Novel Drug Delivery Technology Platform<sup>1,2</sup>

- Intra-tumoural drug delivery
- **Manufactured using FDA-approved biomaterials**
- **Delivers diverse drug payloads:** Approved medicines and in-development drugs (small molecule, biologics, antibody-drugs, mRNA and others)

↑  
**Higher Focused Dose**

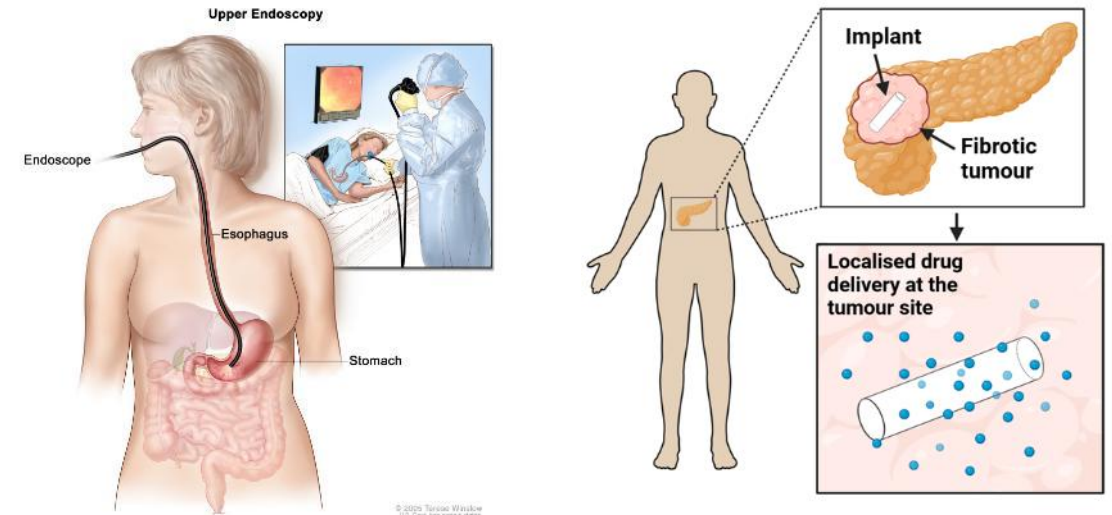
↓  
**Lower Systemic Toxicity**



## Lead Program: Pancreatic Cancer

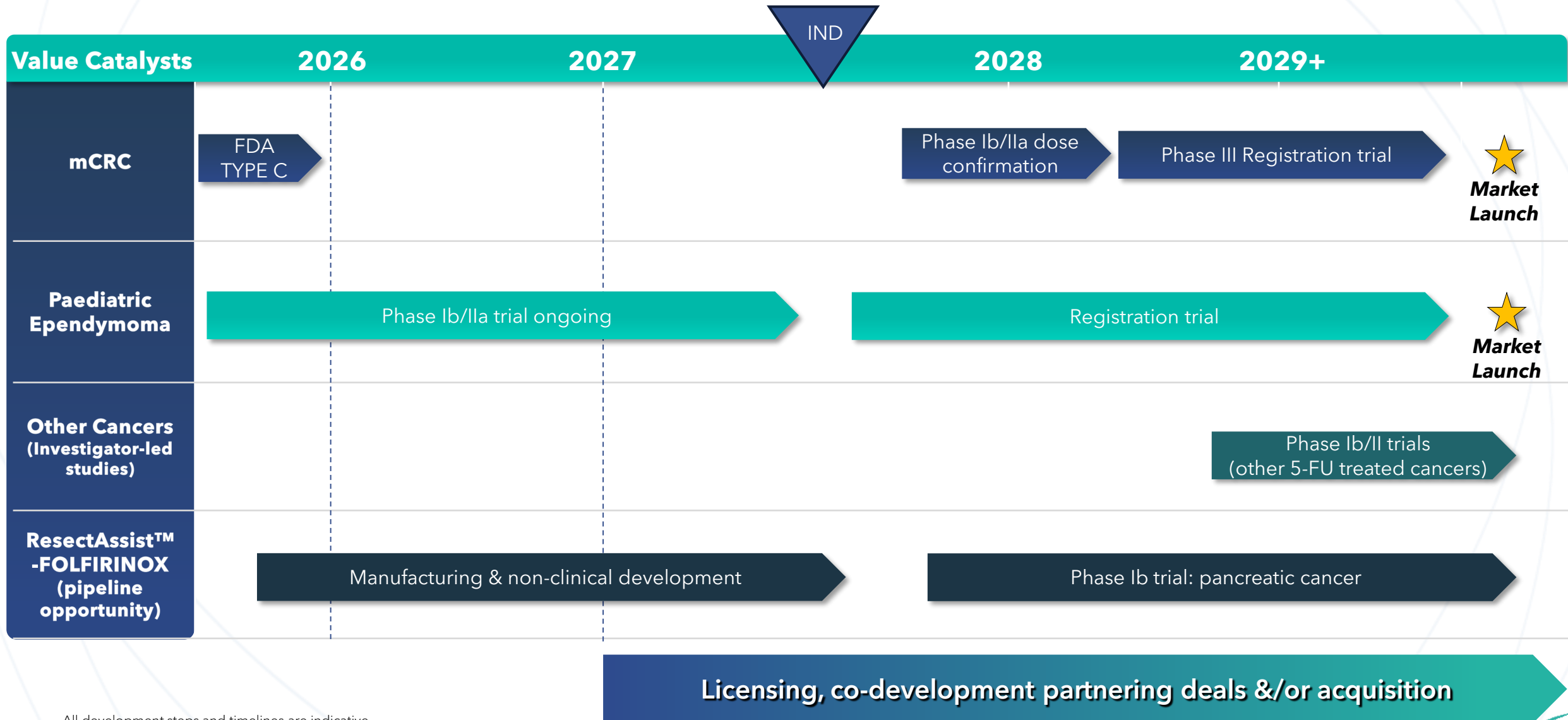
**ResectAssist™-FOLFIRINOX: Downstaging tumours to resectable with curative intent**

- ✓ **Unmet Market:** >\$7B market opportunity<sup>3</sup>
- ✓ **Strong IP:** Composition of matter patents & IP pipeline, including novel drug payload - device combinations
- ✓ **Govt Grant:** \$500K Federal AEA Ignite grant
- ✓ **National Recognition:** 2025 Shaping Australia "Problem Solver" Award Winner



# VALUE CREATION STRATEGY

FivepHusion's fast-tracked development strategy to global markets



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

# ASX LISTED ONCOLOGY PEERS

FivepHusion aims to bridge the valuation gap to its comparable listed peers

Peer	ASX Ticker	Description	Lead Candidate Clinical Stage	Market Cap
Telix	TLX	Telix is specialising in radiopharmaceuticals for cancer diagnosis and therapy.	Phase III Commercialisation	\$4,728m
CLARITY	CU6	Clarity is targeting membrane antigen (PSMA)-expressing metastatic castration-resistant prostate cancer.	Phase III	\$1,210m
RACURA ONCOLOGY	RAC	Racura is reformulating a version of bisantrene, a chemotherapy targeting acute myeloid leukaemia (AML) with potential applications in breast cancer and clear cell renal cell carcinoma (ccRCC).	Phase II	\$499m
starpharma	SPL	Starpharma is developing its dendrimer technology for pharmaceutical applications, such as cancer. The lead asset DEP® SN38 is a reformulation of SN38, in development for advanced colorectal and ovarian cancers	Phase II	\$213m
Amplia THERAPEUTICS	ATX	Amplia is developing its Focal Adhesion Kinase (FAK) inhibitors for pancreatic cancer	Phase II	\$87m
arovella THERAPEUTICS	ALA	Arovella is developing off-the-shelf cancer CAR-T Cell immunotherapies targeting CD19-positive blood cancers.	Phase I	\$85m
immutep	IMM	Immutep is developing immunotherapies targeting cancer and autoimmune disorders	Phase II	\$66m
IMUGENE Developing Cancer Immunotherapies	IMU	Imugene is developing novel therapies to activate the immune system against cancer.	Phase II	\$66m
Prescient Therapeutics	PTX	Prescient is developing personalised medicine approaches to cancer, including targeted & cellular therapies	Phase II	\$59m

# RECENT ONCOLOGY TRANSACTIONS SHOW LUCRATIVE POTENTIAL DEAL OPPORTUNITIES

Date	Type of Deal	Acquirer/Licensee	Target/Licensee	Stage	Upfront (US\$)	Milestones (US\$)	Total Deal Value (US\$)
Apr-24	Partnership	NOVARTIS	PeptiDream <i>Revolutionizing Drug Discovery</i>	Platform	\$180m	\$2,700m	\$2,880m
Feb-25	Option Agreement	abbvie	xilio THERAPEUTICS	Multiple	\$52m	\$2,100m	\$2,152m
Dec-24	Partnership	GSK	DualtyBio 映恩生物	Multiple	\$30m	\$975m	\$1,005m
Nov-24	Partnership	KURA ONCOLOGY	Kyowa KIRIN	Phase 3	\$330m	\$1,200m	\$1,530m
Jun-24	Option Agreement	Takeda	Ascentage	Phase 3	\$100m	\$1,200m	\$1,300m
Jan-23	Licensing Agreement	Takeda	HUTCHMED	Phase 3	\$400m	\$730m <b>mCRC</b>	\$1,130m
Mar-25	Acquisition	Jazz Pharmaceuticals	CHIMERIX	Phase 3	\$935m	-	\$935m
Jul-24	Licensing Agreement	IPSEN	Day One BIOPHARMACEUTICALS	Phase 3	\$111m	\$350m <b>Paediatric brain</b>	\$461m
Mar-26	Acquisition	SERVIER	Day One BIOPHARMACEUTICALS	Commercial	\$2,500m		\$2,500m
Sep-24	Licensing Agreement	sanofi	oranomed	Phase 2	\$110m	\$250m	\$360m
Jan-25	Acquisition	GSK	IDRx	Phase 1b	\$1,000m	\$150m	\$1,150m
May-24	Licensing Agreement	NOVARTIS	ARVINAS	Phase 1	\$150m	\$1,000m	\$1,150m
Jan-25	Licensing Agreement	MENARINI group	Insilico Medicine	Phase 1	\$20m	\$550m	\$570m
May-24	Acquisition	NOVARTIS	mariana ONCOLOGY	Preclinical	\$1,000m	\$750m	\$1,750m

A young child is lying in a hospital bed, wearing a white hospital gown and a white head covering. A stethoscope is visible around their neck. The child is looking upwards and to the right with a slight smile. The background is a soft, teal-colored gradient with white, curved lines on the right side.

# Appendix

## A series of four CEO Interviews summarising the FivepHusion Investment Opportunity

**Interview 1: The scientific and clinical rationale**, focused on Deflexifol® development for metastatic colorectal cancer and paediatric ependymoma ([link](#))

**Interview 2: FivepHusion business fundamentals**, including IP, market opportunities and drug pricing, competitive landscape & revenue projections ([link](#))

**Interview 3: FivepHusion risk differentiation**, in regard to regulatory path, priority indications, development and corporate partnerships ([link](#))

**Interview 4: The FivepHusion investment opportunity**, clinical impact, licensing & M&A opportunities ([link](#))

Posted on the FivepHusion LinkedIn site and The Market Bull website ([link](#))

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

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**

### Phase Ib/IIa trial<sup>^</sup> 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<sup>2</sup> bolus  
+ 3000 mg/m<sup>2</sup> infusion

**Result: Stable Disease**  
5 months

### Pancreatic Cancer

**Patient:** female, 75 years

**Failed two lines previously:**

- FOLFIRINOX
- Gemcitabine/Abraxane

**Treatment: Deflexifol®**

- 525 mg/m<sup>2</sup> bolus  
+ 3000 mg/m<sup>2</sup> 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<sup>2</sup> bolus  
+ 3800 mg/m<sup>2</sup> infusion

**Result: Partial Response**  
6 months

<sup>^</sup> 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%

# FP101B: HREC APPROVED PHASE Ib/IIa TRIAL DESIGN STUDY<sup>^</sup>

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

## Trial Design

- **1<sup>st</sup> line unresectable mCRC**
- **Two stage phase Ib/IIa** Trial Design
  - **40 - 50 patients**; trial duration **~12 months**
- Allarity Therapeutics collaboration: Blinded evaluation of DRP<sup>®</sup>-5-FU CDx predictive ability

## Endpoints

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

### PART A

#### Dose Escalation Cohorts (3 + 3)

(9 - 18 pts, 3 trial sites; ~6 - 8 months<sup>Ⓞ</sup>)

#### Standard of Care

**OXALIPLATIN**

85 mg/m<sup>2</sup>

**BEVACIZUMAB**

5 mg/kg



**DEFLEXIFOL<sup>®</sup>**

**BOLUS<sup>#</sup>**

400 mg/m<sup>2</sup>



**DEFLEXIFOL<sup>®</sup>**

**INFUSION<sup>Ω</sup>**

Dose: → **2400 mg/m<sup>2</sup>**

**3400 mg/m<sup>2</sup>**



No DLTs

**3000 mg/m<sup>2</sup>**



No DLTs

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



### PART B

#### Expansion Cohort

(~30 pts, 6 - 8 trial sites; ~6 months<sup>Ⓞ</sup>)

**OXALIPLATIN**

85 mg/m<sup>2</sup>

**BEVACIZUMAB**

5 mg/kg



**DEFLEXIFOL<sup>®</sup>**

**BOLUS**

400 mg/m<sup>2</sup>



**DEFLEXIFOL<sup>®</sup>**

**INFUSION**

Part A MTD

<sup>^</sup> Trial design approved by Bellberry HREC. Trial planned to commence H1 2026, 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

<sup>#</sup> Deflexifol<sup>®</sup> bolus = 400 mg/m<sup>2</sup> 5-FU + 27 mg/m<sup>2</sup> LV;  
<sup>Ω</sup> Deflexifol<sup>®</sup> infusion dose escalation = 2400 mg/m<sup>2</sup> 5-FU + 160 mg/m<sup>2</sup> LV (equivalent to the current standard 5-FU dose) up to the currently declared MTD of 3400 mg/m<sup>2</sup> 5-FU + 227 mg/m<sup>2</sup> LV

## 1st line treatment of unresectable mCRC

### Phase III Registration Trial

- International, multi-centre registration trial
- Designed to demonstrate that as a treatment for first-line unresectable mCRC,
  - *Deflexifol<sup>®</sup> in combination with oxaliplatin and bevacizumab (DEFLOX)*
- is superior in efficacy to\*
  - *the standard of care mFOLFOX6 + bevacizumab regimen*

### Rationale for superior efficacy over the standard of care

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

### GLOBAL PHASE III TRIAL

A ~550 patient, blinded, randomized phase III study of Deflexifol<sup>®</sup> 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

# EPENDYMOMA SENSITIVITY TO 5-FU

Ependymoma (EPN) = 3<sup>rd</sup> Most Common paediatric brain tumour<sup>1</sup>

Ependymoma cell lines have significantly lower *thymidylate synthase* expression levels<sup>2,3</sup> → **increased 5-FU sensitivity**

**Posterior fossa (PF)**  
~2/3 of childhood EPN<sup>1</sup>



**Supratentorial**  
~1/3 of childhood EPN<sup>1</sup>

All partial responders in the St Jude 5-FU trial had primary PF-EPN<sup>4</sup>

**PF-A** = ~85-90% of PF-EPN<sup>1</sup>

- Predominantly younger children
- Frequent gain of chromosome arm 1q (1q+)<sup>5</sup>
  - ~20% at presentation
  - ~50% at first recurrence

**PF-B** = ~10-15% of PF-EPN<sup>1</sup>

- Mostly older children & adults

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<sup>6</sup>*



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

<sup>1</sup> Zaytseva et al. 2021, *Cancers* 13(19):4954.

<sup>2</sup> Atkinson et al. 2011, *Cancer Cell* 20(3):384-99.

<sup>3</sup> Donson et al. 2018, *Mol Cancer Ther.* 17(9):1984-94.

<sup>4</sup> Wright et al. 2015, *Neuro Oncol.* 17(12):1620-27.

<sup>5</sup> Donson et al. 2023, *Neuro Oncol.* 25(10):1854-67.

<sup>6</sup> Griesinger et al. 2024, *Clin Cancer Res.* 30(8):1544-54.

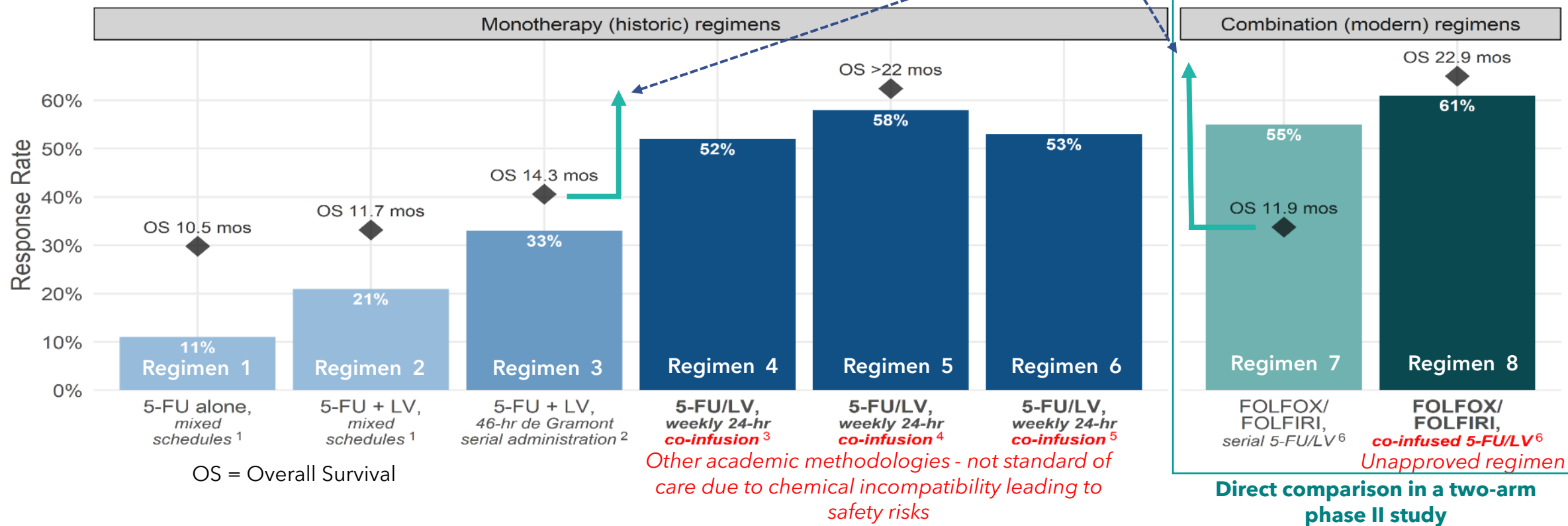
# 5-FU/LV Co-Infusion Improves Anti-Tumour Efficacy

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

mCRC 1<sup>st</sup> 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).
- FivepHusion's Phase III trial will aim to outperform results from Regimen 7:
  - Results anticipated to **meet/exceed Regimen 8, resulting in successful approval**

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



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. Ardanal 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

# 5-FU/LV CO-ADMINISTRATION: PRECEDENTS & COMPARISON

Deflexifol® is clinically and commercially viable

Two separate pumps <sup>1</sup>	Dilution strategies <sup>2-3</sup>	Sodium salt LV <sup>4-5</sup>	Deflexifol®
<ul style="list-style-type: none"><li>✓ Considerably improved survival &amp; response rate in untreated &amp; previously treated mCRC patients.<sup>1</sup></li><li>✗ <b>Not clinically or commercially feasible</b> - requires two pumps &amp; intravenous lines.</li></ul>	<ul style="list-style-type: none"><li>✓ Considerably improved response rates in untreated &amp; previously treated mCRC patients.<sup>2,3</sup></li><li>✗ <b>Does not prevent precipitation</b> and catheter blockages.</li><li>✗ <b>Not approved</b> for this usage.</li></ul>	<ul style="list-style-type: none"><li>✓ Significantly improved patient survival in 1<sup>st</sup> line mCRC when used in modern infusion regimens.<sup>4,5</sup></li><li>✗ <b>Not approved</b> for this usage.</li><li>✗ <b>Requires alkaline pH of 9.0.</b></li><li>✗ <b>Similar toxicity to standard dose administration.</b></li></ul>	<ul style="list-style-type: none"><li>✓ <b>No precipitation</b> or catheter blockages.</li><li>✓ Pain-free, <b>physiological-pH</b> formulation.</li><li>✓ Highly tolerable, with a <b>higher MTD than 5-FU.</b></li><li>✓ <b>Improved safety.</b></li><li>✓ <b>Demonstrable efficacy</b> in end-stage patients following previous 5-FU failure.</li><li>✓ <b>Composition of matter patent protection.</b></li></ul>

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.**

<sup>1</sup> Ardalan et al., 1991, J Clin Oncol. 9:625.

<sup>2</sup> Yeh et al. 1997, Anticancer Res. 17:3867.

<sup>3</sup> Yang et al. 1999, Cancer 85:1925.

<sup>4</sup> Bleiberg et al. 2012, Acta Gastroenterol Belg. 75:14.

<sup>5</sup> Romano et al. 2021, Oncotarget 12:221.

# 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**<sup>1</sup>
  - Analysts expected \$3,000 - \$6,600/month prior to clinical failure<sup>2,3</sup>

### 5-FU & LV: Current Pricing (\$US)

<b>5-FU + LV: Per month</b>	~\$180 - \$800
<b>5-FU + LV: Per course*</b>	~\$1,500 - \$6,500

### Deflexifol®: Potential Pricing

<b>Low Case (~2x)</b>	~\$1,100/month;	~\$9,000/course
<b>Mid Case (~8x)</b>	~\$4,400/month;	~\$35,000/course
<b>Courses/patient</b>	~2-3x	
<b>Cost/patient</b>	<b>\$18,000 → \$70,000</b>	
<b>COGS</b>	Immaterial	
<b>Cases/annum</b>	mCRC = ~500,000 Other Solid Tumours = 5,000,000+	

<sup>1</sup> Isofol Medical AB, IPO Prospectus 2017; Isofol Medical, Arfolitixorin overview, 2020

<sup>2</sup> DNB Markets, Isofol Medical Equity Research 15 Nov 2020; Redeye research update Isofol Medical, 15 Nov 2020

<sup>3</sup> Wolters Kluwer Medi-Span Price Rx Accessed May 2020

\* An average course of treatment is 8 months

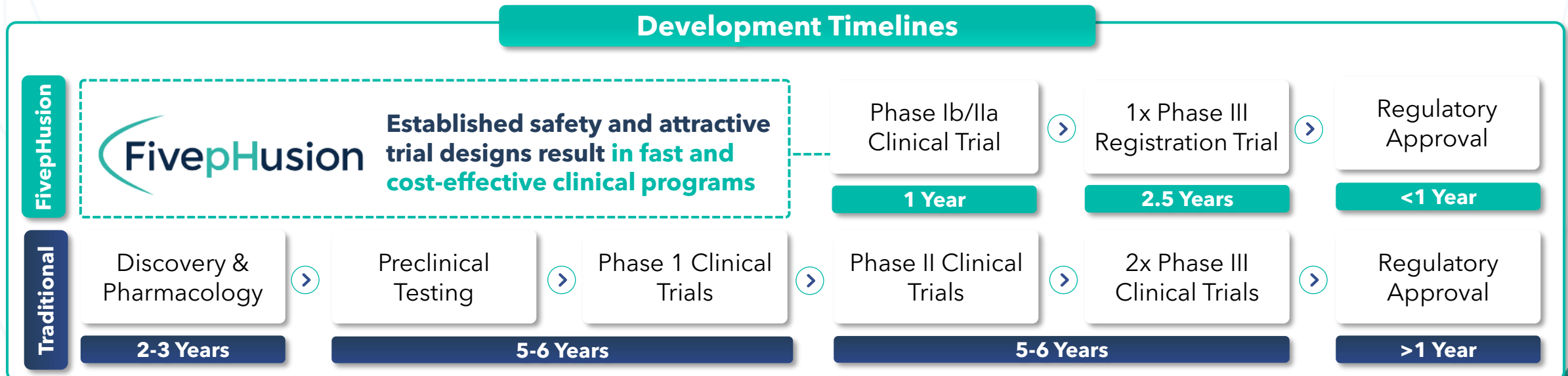
Pricing data sourced from published literature and national pricing & reimbursement authorities (e.g. CMS, G-BA, NICE, AIFA, etc). Prices differ across geographic regions and are subject to change over time due to changes in legislation, demand, shortages, and other factors, thus prices listed on this slide may be subject to change in the future.

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

# FIVEPHUSION VS. TRADITIONAL BIOTECH

FivepHusion's unique co-formulation strategy delivers a rare value proposition

	Cost	Timelines	Risk Profile	1 <sup>st</sup> Line Therapy	Strong IP	Blockbuster
<b>FivepHusion</b>	✓ Low	✓ Short ~3.5 Years	✓ Low Safety & Efficacy Established	✓ Yes	✓ Yes Composition of Matter	✓ Yes
<b>Traditional</b>	✗ High	✗ Long 13-16 years	✗ High Safety & Efficacy Unproven	✗ Rarely	✓ Yes Composition of Matter	✓ Yes



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

## Blockbuster Markets

- **1.9m colorectal cancers diagnosed** p.a. ( $\leq 570k$  metastatic) = **US\$13B mCRC market**
- **8.0m+ solid tumour diagnosed** p.a. (where 5-FU + LV are utilised)

## First-Line Therapy

- 5-FU + LV: Established standard of care' backbone therapy for mCRC (95% of patients)
- **Deflexifol®: 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

- 5x independent surrogate Phase II trials confirm rationale and therapeutic mechanism
- 3x company clinical trials demonstrated **higher safety & tolerability** and **potent efficacy**

## Fast-tracked and Capital-Efficient

- Fast-tracked development via 505(b)(2) pathway **enabling faster, lower cost approval**
  - Phase Ib/IIa + **single pivotal Phase III** → ~3.5 years to approval
  - Rare in oncology: Deflexifol® is a 'next generation' co-formulation (with composition of matter patents), differing from basic reformulations or new delivery methods.

## Strong FDA Engagement

- Ongoing FDA dialogue, including Type C Meeting, guiding Phase Ib/IIa and Phase III trial designs (mCRC)

## Significant Pipeline

- **Active Phase I/II paediatric brain cancer** trial moving towards a pivotal trial.
- **Broader applications where 5-FU + LV are utilised:** pancreatic, gastric, breast, head & neck cancers

## IP Protection

- **Granted Composition of Matter patents**, expected **exclusivity to >2045**

## Licensing Transactions

- Clear, short-term pathway to **regional and global licensing transactions**