

Deflexifol

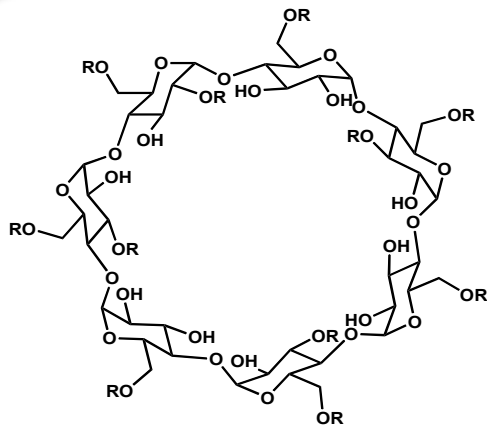
Accelerated Route-to-Market Oncology Reformulation Offering Increased Efficacy and Patient Tolerability

Highlights

- Deflexifol is a reformulation of Fluorouracil (5-FU) and Leucovorin (LV) with a superior therapeutic profile
- Deflexifol can replace 5-FU & LV in SOC (FOLFOX/FOLFIRI)
- Colorectal cancer (CRC): US 8\$b market
- 1.2m new cases/yr globally; 600k deaths/yr; 150k 5-FU scripts/yr in Australia alone
- Widely patented; Straightforward manufacture, ~ cost of goods
- Premium pricing precedents: Doxil, Abraxane (>10x)
- FDA pre-IND => 505(b)(2); Phase I trial completed
- Updated regulatory review - 1 more confirmatory trial required for NDA
- Planned IND mid-2019; NDA 2021

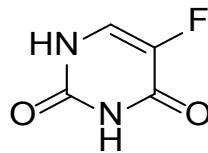
CRC Challenges and Solutions

- Colorectal Cancer Standard of Care regimens:
24 of 29 include 5-FU & Leucovorin
- 5-FU potency enhanced by LV
- BUT these 2 drugs are chemically incompatible
- => Reduced efficacy, increased side effects



Cyclodextrin

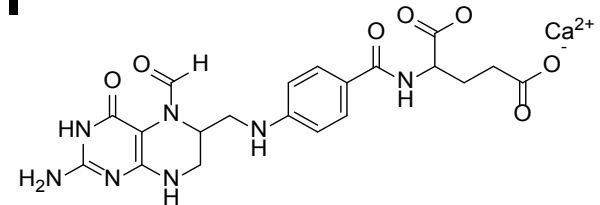
Deflexifol



+

5-FU

+



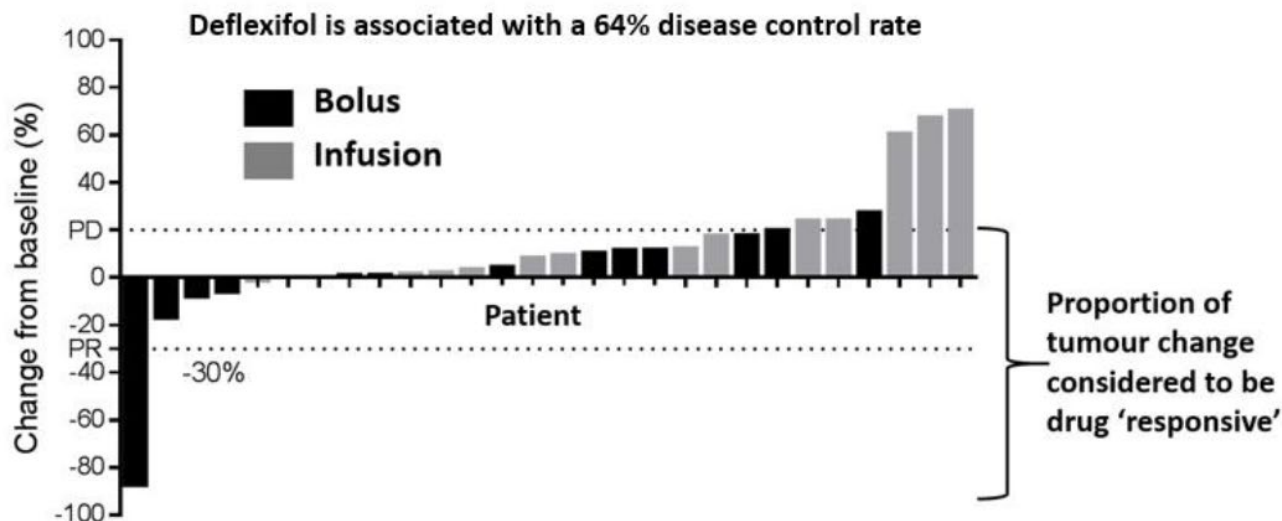
Leucovorin

All APIs FDA approved for injection



Phase I Trial Results

- 40 patients treated
- 64% of patients had disease control (80% had failed prior 5-FU)
- Pharmacokinetics similar to 5-FU
- Much lower toxicity than SOC
 - No grade IV toxicity at any dose level, including @ 3600mg/m² infusional (50% higher than SOC)
- 25+% increase in therapeutic dose of 5-FU



FivepHusion Team

- Strong scientific and clinical expertise
- Successful capital raise to fund phase I
- Completed phase I
- Detailed plans for cGMP, final CMC, CRO led phase IIb
- Regulatory - pre-IND; updated regulatory advice from Ground Zero Pharmaceuticals (USA)
- Business Development advisors - Bio-Link Australia

Seeking Partner for Exclusive Licensing or Co-Development

- Currently funded to IND
- Ideal partner has strong development, regulatory and marketing expertise
- Seeking funding for confirmatory trial, NDA, market positioning, reimbursement
- Exit Proposal:
 - Entry to +US\$1b market in 2021 following 505(b)(2) NDA
 - Licensing of world-wide rights for milestone payments + royalties on product sales

DEFLEXIFOL THE NEW STANDARD FLUOROPYRIMIDINE CHEMOTHERAPY

Dr Andrey Coley
[Business Development](#)
a.coley@bio-link.com

David Ranson
Chairman
rdranson@fivephusion.com

www.fivephusion.com

