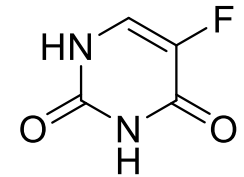


Deflexifol

An improved chemotherapy

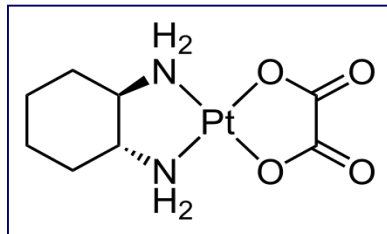
The new standard in
fluoropyrimidine therapies

5-Fluorouracil (5-FU)



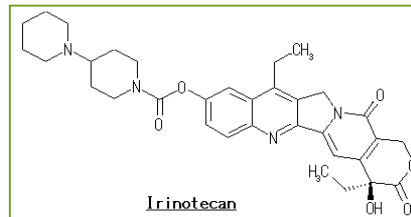
- CRC standard of care = 5-FU + Leucovorin (LV) with or without:

oxaliplatin



FOLFOX

irinotecan



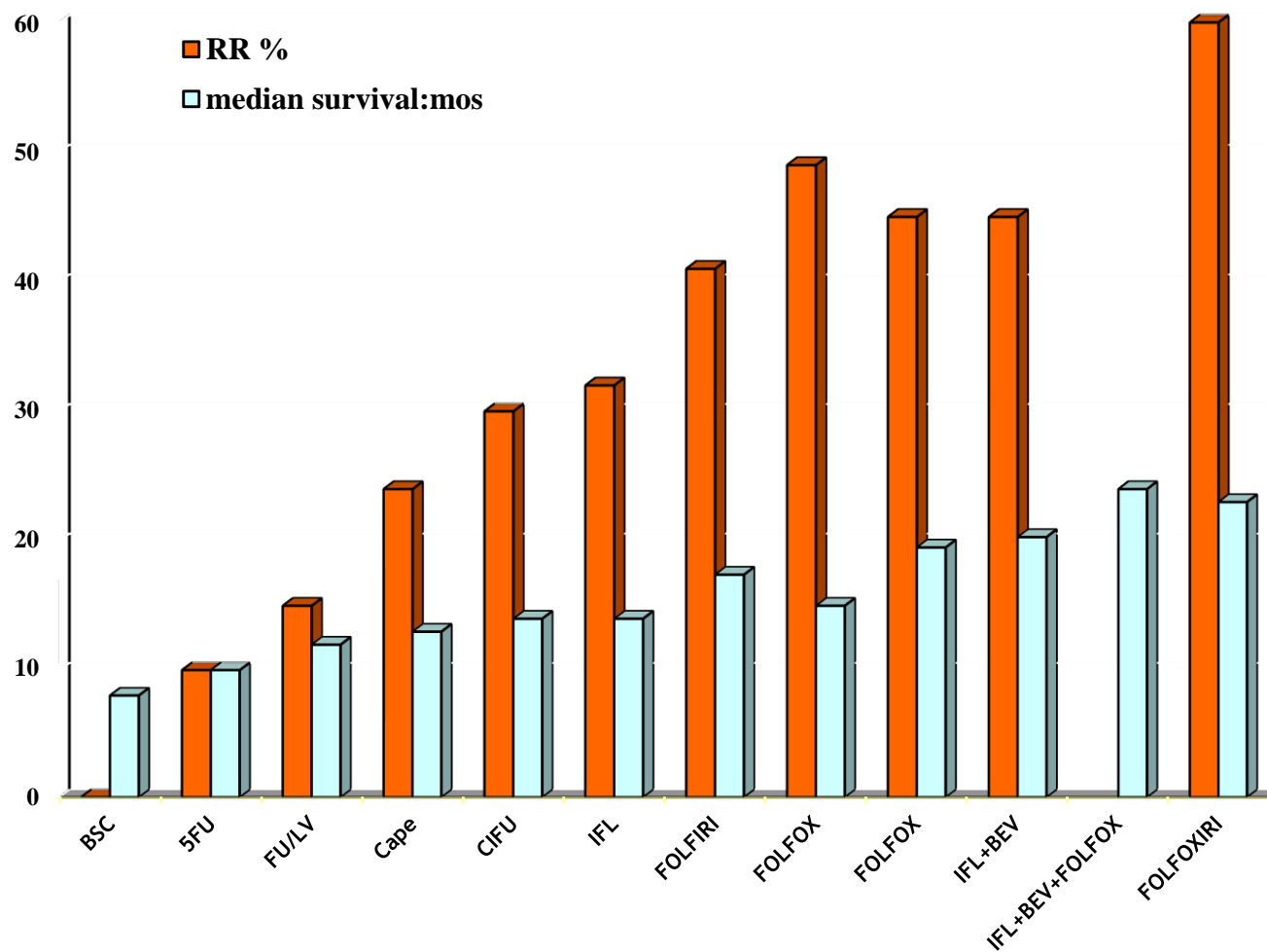
FOLFORI

biologics



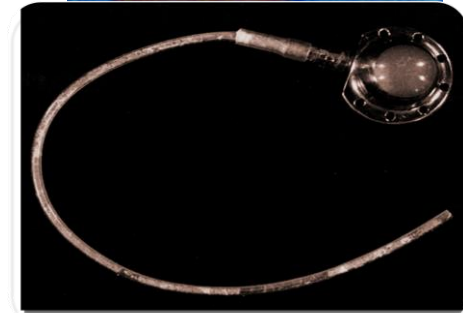
Anti-VEGF
Anti-EGFR

Evolution of therapy for CRC



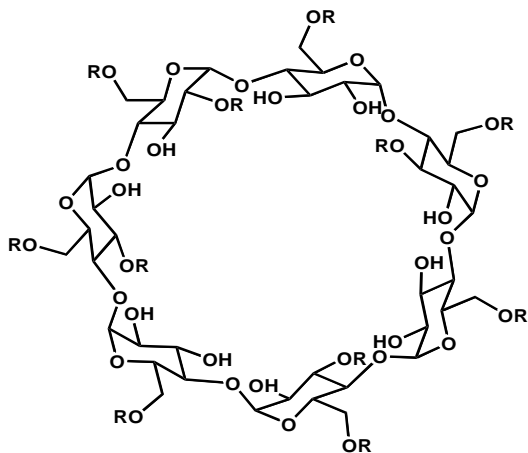
Problems

- 5-FU is alkaline (pH 9) => venous collapse & severe pain
- 5-FU & LV must be administered separately
- => reduced efficacy for infused 5-FU
 - A phase 2 trial demonstrated greatly improved response rate if 5-FU + LV infused together. BUT 50% catheter blockage.



An all-in-one pH neutral solution

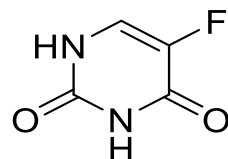
Deflexifol



HP-β-CD

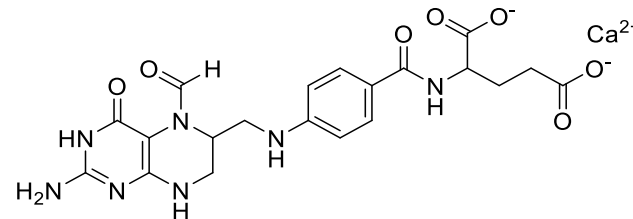
R = CH₂(CH(OH)CH₃)

100 mg/ml



5-FU

15 mg/ml



leucovorin

1 mg/ml

All APIs FDA approved for injection

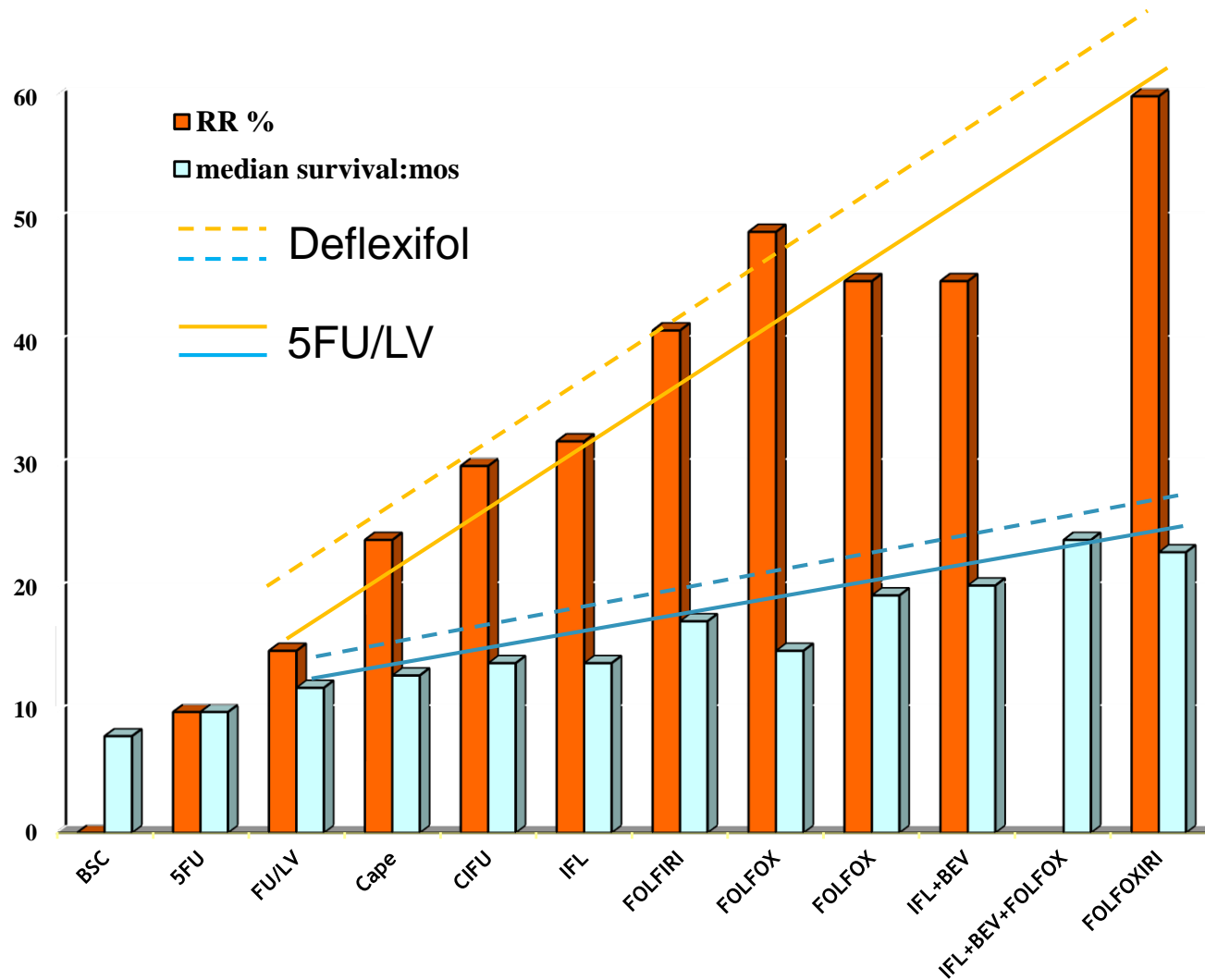
Patents approved in US, CN, EU, CA, AU



Phase 1 trial results

- 69% of patients had disease control
 - GI, Breast, Head & Neck cancer patients that had failed all other treatments including 5-FU regimens
- 25+% increase in therapeutic dose of 5-FU
- Much lower toxicity than expected
 - No grade IV toxicity at any infusional dose level, including @ 3600mg/m²
- Pharmacokinetics similar to 5-FU
- ASCO 2017 presentations: Clingan P.; Ackland S.

Future of therapy for CRC?



Target Market

- Colorectal & other GI, breast, head and neck....
 - ❑ Intra-arterial chemotherapy?
- 1.2 million new CRC cases/year; 600,000 deaths
 - ❑ 56% present with stage III or IV in US
- Mainstay of therapy for stage III/IV is 5-FU & LV plus...
 - ❑ Of 29 approved CRC protocols, only 5 do not include 5-FU and LV
 - ❑ 68% of mCRC patients in Australia receive 5-FU & LV
- Sales of CRC drugs > US\$5 billion in 2013
 - ❑ Bevacizumab (Avastin) \$6.75b, Cetuximab (Erbix) \$1.7b, etc

Commercialisation Strategy

- Out-license to pharma or raise \$4 million VC in stages
- Hybrid phase II trial vetted by FDA under 505(b)(2) path
 - Approved for sale in 2-3 years?
- Exit via float, out-license or raise capital to:
 - Commence marketing, reimbursement
 - Phase III trial to measure improved efficacy

**DEFLEXIFOL HAS THE CAPACITY TO
BECOME THE NEW STANDARD
FLUOROPYRIMIDINE**