

## Best-in-Class Safety

**Fig. 4: P3 bDMARD-IR RA Safety - FINCH 2 vs. SELECT-BEYOND**

Green highlighted cells highlight better drug by listed AE.

Drug (Name of Pivotal Trial) Assessment Period Trial Arm n	Upadacitinib (P3 SELECT-BEYOND)					Filgotinib (P3 FINCH 2)		
	PBO 169	Weeks 0-12		Weeks 12-24*		PBO 148	Week 24	
		High Dose 164	Low Dose 165	Low Dose 228	High Dose 223		Low Dose 153	High Dose 147
Serious AE	0 (0.0%)	8 (4.9%)	12 (7.3%)	10 (4.4%)	10 (4.5%)	5 (3.4%)	8 (5.2%)	6 (4.1%)
PE/DVT	0 (0.0%)	1 (0.6%)	1 (0.6%)	3 (1.3%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Deaths	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%) <sup>^</sup>
Herpes Zoster	1 (0.6%)	1 (0.6%)	4 (2.4%)	2 (0.9%)	3 (1.3%)	0 (0.0%)	2 (1.3%)	2 (1.4%)
Serious Infections	0 (0.0%)	1 (0.6%)	4 (2.4%)	3 (1.3%)	3 (1.3%)	?	?	?
Opportunistic Infections	0 (0.0%)	1 (0.6%)	2 (1.2%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Malignancy	1 (0.6%)	1 (0.6%)	2 (1.2%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MACE	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.4%)	1 (0.7%)	1 (0.7%)	0 (0.0%)

\* Week 12-24 Includes PBO switches to Upa 15 or Upa 30mg

<sup>^</sup> 1 case of retinal vein occlusion, non-serious

Source: Company reports, Instinet research

**Fig. 5: Filgo Safety Summary vs. other bDMARDs**

event per 100 PYE	filgotinib 50-200 mg DARWIN3 wk132	baricitinib 2 and 4 mg QD Genovese et al ACR2017	tofacitinib 5 mg BID Wollenhaupt ACR 2017	upadacitinib 6 and 12 mg BID Genovese ACR2017	tocilizumab 4 and 8 mg/kg Genovese ACR 2012	adalimumab Burmester 2011
patient year exp.	2,042	6,637	5,278	725	14,994	23,943
serious infection	1.0	2.9	2.4	2.3	4.5	4.6
herpes zoster	1.5	3.2	3.8	3.7	ND	ND
DVT/PE	2/2,042 <sup>†</sup> 0.1	31/6,754 0.5	3/1,849 0.2	5/725 0.7	ND	ND
deaths	0.2	0.3	0.6	0.3	0.6	0.8

<sup>†</sup>: one single patient experiencing DVT and PE

DVT/PE = deep venous thrombosis/pulmonary embolism

Notes: data not from head-to-head studies, comparisons may not be accurate

Tofacitinib DVT/PE data from Mease, ACR2017 (5mg bid), and death data from 2012 FDA Medical review

Baricitinib DVT/PE Weinblatt ACR 2017

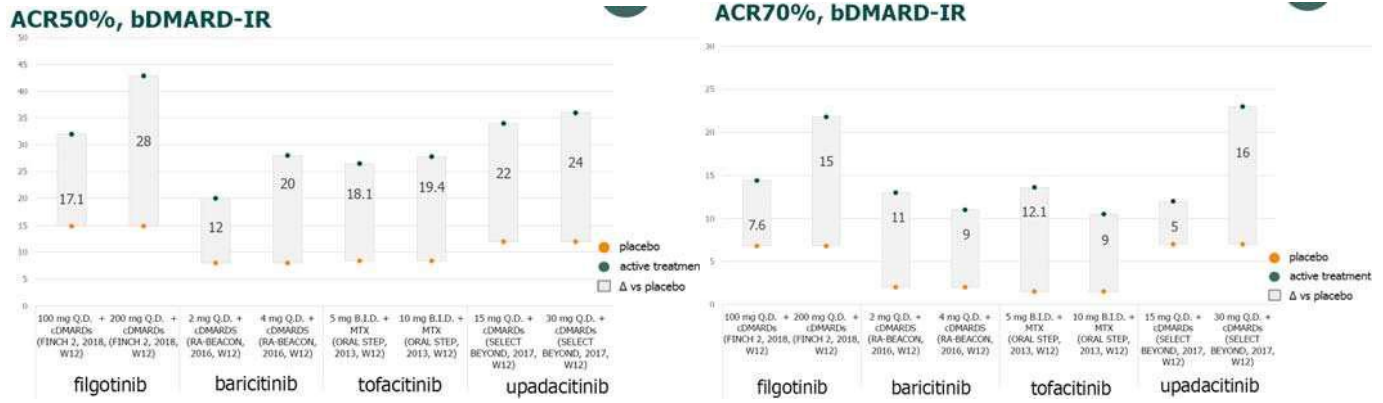
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Galapagos

Source: Company presentations

## Efficacy ≥ Competing JAKis and Biologics Across Indications

**Fig. 6: FINCH 2 – Filgo Efficacy Comparisons vs. Other JAK inhibitors (wk12)**



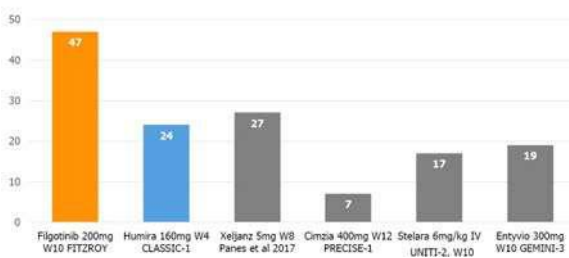
Source: Company presentations

**Fig. 7: P2 Filgo Results Shows Potential for Best-in-Class Efficacy Across Indications**

### Activity in CD, TNF naive

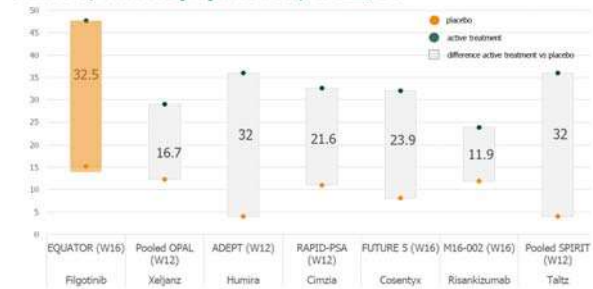
Clinical remission: induction

Active delta to placebo, % responders



### Activity in psoriatic arthritis

ACR50, mixed population, W12/16

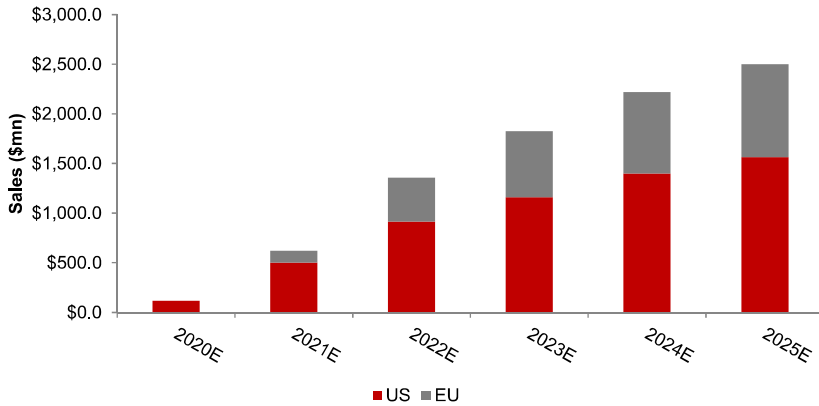


Source: Company presentations

# Filgotinib Revenue Est. - By Indication

## Rheumatoid Arthritis (~\$2.5bn)

Fig. 8: Rheumatoid Arthritis – Filgotinib Revenue Estimates

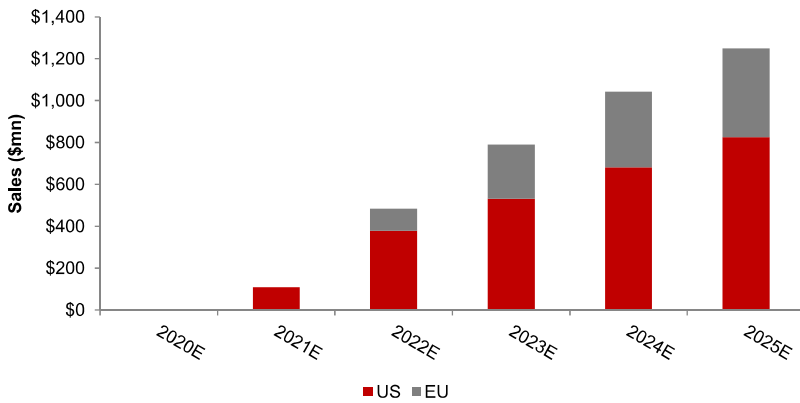


- [FINCH 2 note](#)
- Launch 2H20E
- Peak Sales: \$2.5bn by 2025E.
- Despite being the fourth JAK inhibitor, filgotinib to enter the saturated RA market (~1 yr after ABBV's Upa), we believe filgotinib's best-in-class safety profile and strong efficacy, on par with other bDMARDs, will garner strong uptake to ~\$2.5bn WW.
- FINCH 1 and 3 in early-line RA are expected to readout in 1Q19E.

Source: Instinet estimates

## Ulcerative Colitis (~\$1.25bn)

Fig. 9: Ulcerative Colitis – Filgotinib Revenue Estimates

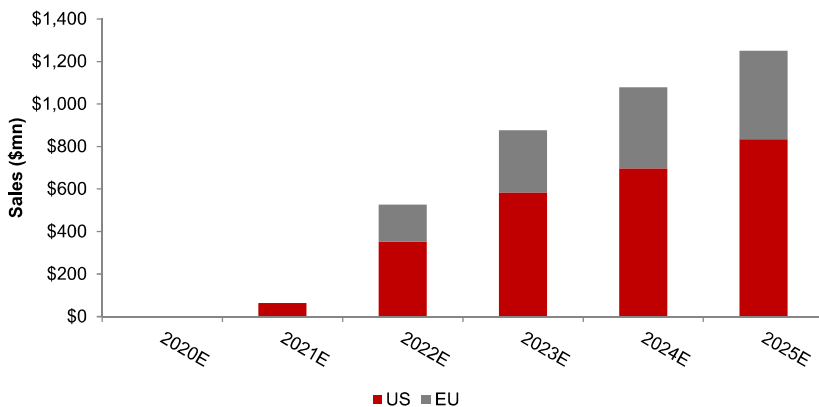


- P2/3 SELECTION 1 Proceed to P3 [Note](#)
- Launch 1H21E
- Peak Sales: \$1.25bn by 2025E
- GLPG anticipates enrollment completion in the P3 SELECTION 1 trial by 1H19E – we expect to be early 1Q19E, based on GILD's focus on MANTA UC enrollment.
- We expect top-line readout either by YE19 or 1Q20.
- With Xeljanz (approved) and Upa showing activity in UC, we est. filgo will improve upon efficacy and safety, respectively – similar to RA.

Source: Instinet estimates

## Crohn's Disease (~\$1.25bn)

Fig. 10: Crohn's Disease – Filgotinib Revenue Estimates

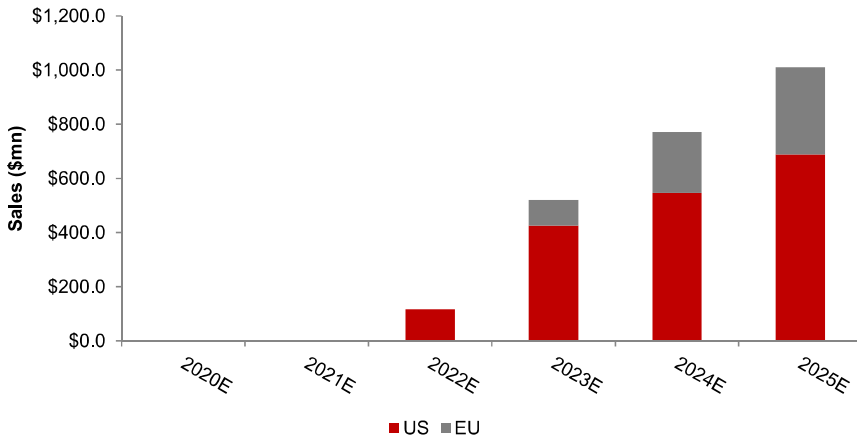


- Launch 2H21E
- Peak Sales: \$1.25bn by 2025E
- GLPG anticipates enrollment completion in the P3 DIVERSITY 1 trial by 2H19.
- We expect top-line readout in 2H20.
- Based on robust P2 results in FITZROY trial in TNF-naïve patients 47% active delta vs. placebo (induction of remission), we believe filgo will improve substantially upon SOC and garner strong uptake in Crohn's disease where there is strong unmet need for efficacy.

Source: Instinet estimates

### Psoriatic Arthritis (~\$1.0bn)

Fig. 11: Psoriatic Arthritis – Filgotinib Revenue Estimates



- **P2 data note**
- Launch 2022E
- We anticipate Phase 3 Start in 2019.
- P2 data was vastly superior to Xeljanz PsA pivotal and other bDMARDs.
- At the R&D day, mgmt. announced filgo demonstrated pain benefits independent of anti-inflammatory MOA – to be revealed in the future. Strong benefits in QoL will help filgo compete in PsA.
- Psoriasis better picked up by IL-17 and IL-23. Vast majority has tendonitis for which JAKi is better MOA.

Source: Instinet estimates

### MANTA - GILD 3Q Earnings Call

Consistent with prior guidance, MANTA data is required for filing (as of now). MANTA is a trial (n=250) evaluating the testicular safety of filgo in adult UC males on a 13-wk primary endpt of >50% decrease vs. baseline in sperm concentration. MANTA’s Jan 2021 primary completion and 26-week secondary endpts worry some investors.

#### GILD 3Q Call – Bullish – FINCH 1 & 3 Readout Now 1Q19E

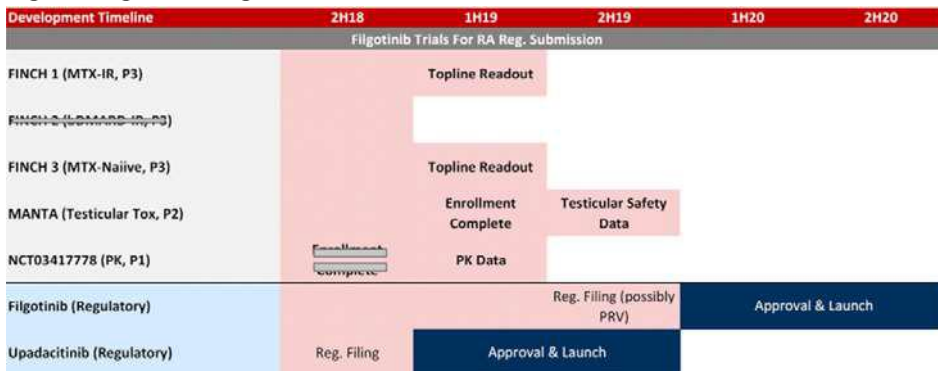
On the 3Q earnings call, GILD narrowed the expected timing of FINCH 1 & 3 readout from 1H19 to **1Q19**. Investor Qs focused on MANTA– no clarity on speed of enrollment.

**During Q&A, GILD’s R&D Head confirmed a submission with MANTA appended at the end is one possible option – they are currently discussing with regulators.**

There were also hints at potential modifications to inclusion criteria in MANTA (maybe add Crohn’s? No placebo?) - in order to speed enrollment. We note 70 sites are up and recruiting (for a P2 study) – indicating GILD’s working diligently to enroll ASAP.

We est. brisk enrollment complete in 1H19 w/ primary endpt 13-wk data avail. for 2H19 FDA filing. MANTA is an overly conservative FDA study req., in our view, given the expected increase in sperm count with reduction in inflammation. Regardless, MANTA timelines don’t change expectations that filgo would launch shortly after upa.

Fig. 12: Filgotinib Program – Estimated Milestones



Source: Company reports, Instinet estimates