Uneventful 1Q Financials; Eagerly Await FDA Need for MANTA Around Mid-Year

29 April 2019

Key Takeaway

Following positive filgotinib FINCH data, suggesting a potentially best in class safety profile, we raise our probability of success to 80% (from 70%), driving our +8% increased PT. We eagerly await the outcome of planned FDA meeting during 2Q19E to glean greater visibility on timings for US filings. Pipeline updates include novel JAK1/TYK2 inhibitor, GLPG3121, starting Phase I, and plans for a PoC study for first Toledo compound, GLPG3312, in UC by YE19E.

1Q19 financials immaterial

2019 guidance for €320-340m cash burn reiterated, with JEFe €340m in-line.

Filgotinib FINCH efficacy in-line, safety reassures on potentially differentiated profile

Efficacy data from the 3 Phase III FINCH trials in RA suggest filgotinib's efficacy is similar to key competitor upadacitinib. On our recent roadshow, management highlighted that the totality and consistency of efficacy data, together with potentially two doses, which clinicians appreciate in chronic conditions, position filgotinib well as the fourth JAKi to market. Importantly, with comparable efficacy and best in class safety, avoiding the typical thrombotic events associated with the JAKi class, filgotinib could be considered to have a better risk:benefit profile than other JAKi, with this differentiated safety profile potentially key to driving use.

MANTA male safety study could be the rate-limiting step

Partner Gilead has requested a meeting with US FDA to discuss the existing dataset and the possibility of filing on FINCH data, with results from the ongoing Phase II MANTA male safety trial then submitted later. Once there is clarity from the FDA on the path forward, Gilead should update on timing for MANTA data if this is required for filing. Galapagos is sponsoring the MANTA-RAy study, which expands upon MANTA to include rheumatic diseases and permitting a broader age range, seeking to enrol a total of c.250 patients across both studies, with 200 required by the FDA to assess sperm counts.

Regulatory filings in Europe and Japan are expected in 3Q and 4Q19E, respectively.

Multi-blockbuster potential for filgotinib

We forecast $6bn WW peak sales, with $3bn in RA, $600m in Crohn's disease, $400m in ulcerative colitis, and a $2bn cumulative contribution for other indications, for c. €85/share NPV with a 80% probability of success. 2H19E Phase II data in Sjögren's syndrome and forms of lupus could support our view of the broad commercial potential, with a Phase III in psoriatic arthritis to start in 2019E and potentially also in ankylosing spondylitis.

Pipeline rightfully gaining attention

GLPG1690 is in the Phase III ISABELA programme in lung fibrosis (IPF) and a Phase II in systemic sclerosis. We forecast $850m WW '1690 peak sales in IPF after 2022E launch. The Phase II ROCCELLA and PINTA trials of GLPG1972 in osteoarthritis and GLPG1205 in IPF, respectively, are also in progress. Phase I data for the first Toledo compound, GLPG3312, are expected in 2H19E.

Target | Estimate Change	
RATING	BUY
TICKER	GLPG NA
PRICE	€100.85^
PRICE TARGET (PT)	€130.00 (from €120.00)
MARKET CAP	€5.5B / $6.1B

^Prior trading day's closing price unless otherwise noted.

RATING	BUY
TICKER	GLPG
PRICE	$112.86^
PRICE TARGET (PT)	$145.00 (from $136.00)
MARKET CAP	€5.5B / $6.2B

^Prior trading day's closing price unless otherwise noted.

FY Dec	2018A	2019E	2020E	2021E
EPS (€)	(0.56)	↑ (3.86)	↑ (3.99)	↑ (4.49)
Previous		*(4.01)*	*(4.06)*	*(6.55)*
FY P/E	NM	NM	NM	NM

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The Long View

Scenarios

Base Case

- Lead product filgotinib underpins much of our valuation and remains the focus. We are encouraged by its competitive profile in the Phase III FINCH RA programme and Phase II FITZROY Crohn's trial. Partner Gilead should maximise its commercial potential.
- Numerous other pipeline programmes could also crystallise value via possible milestones from existing alliances or new deals, in particular in lung fibrosis (IPF) and osteoarthritis.
- Price Target €130/$145 per share/ADS largely comprising filgotinib, GLPG1690, GLPG1972, and MOR106 NPVs plus Net Cash.

Upside Scenario

- Positive filgotinib data in Crohn's and ulcerative colitis could potentially add c.€10/share
- MOR106 positive Phase II IGUANA results in atopic dermatitis could be worth around €3/share.
- Positive Phase III ISABELA results for GLPG1690 in idiopathic pulmonary fibrosis could add around €19/share.
- These potential catalysts could boost our NPV derived Price Target to c.€160/$178 per share/ADS. Incremental pharma deals or alliances could provide further upside.

Downside Scenario

- Regulatory delays or MANTA safety concerns for filgotinib could remove around €68/share from our valuation.
- Efficacy and/or safety concerns in the filgotinib Phase III Crohn's or ulcerative colitis trials could remove up to €16/share from our valuation.
- Setbacks or delays with MOR106 could remove c.€4/share.
- Efficacy or safety concerns for GLPG1690 in IPF could remove at least €11/share
- These setbacks could reduce our NPV derived Price Target to c.€32/$36 per share/ADS.

Investment Thesis / Where We Differ

- The c.€1.2bn Cash at 31 March 2019 should be more than sufficient to fund operations for the foreseeable future. Our cash burn forecasts exclude potential upsides from incremental deals.
- If successfully developed, Galapagos could commercialise GLPG1690 itself for the Orphan Disease IPF, which could provide a potentially lucrative long-term opportunity.

Catalysts

- Possible update on the US regulatory path for filgotinib around mid-year
- Phase II filgotinib Sjögren's and cutaneous lupus data in 3Q and 4Q19E, respectively
- Filgotinib Phase IIb/III SELECTION ulcerative colitis data in 1Q20E for potential filings during 2H20E
- MOR106 Phase II IGUANA data in atopic dermatitis in 1H20E
- Regulatory approvals of filgotinib for RA during 2H20E.

Long Term Analysis

2018-23E Revenue CAGR	**+6%**
2018 Net Cash (€m)	1,291
2019E Net Cash (€m)	948
2020E Net Cash (€m)	768

Financial Summary and Market Data

Financial Summary	
Long-Term Debt (MM)	€20.4
Cash & ST Invest. (MM)	€1,222.9

Market Data	
52-Week Range:	€111.80 - €70.64
Total Entprs. Value	€4.3B
Avg. Daily Value MM ($)	53.86
Float (%)	86.6%

Estimates and Valuation

Estimates								
€	Prev.	2018A	Prev.	2019E	Prev.	2020E	Prev.	2021E
Rev. (MM)		317.8	187.0	↑ 225.7	210.0	↑ 253.9	65.1	↑ 187.3
EBIT (MM)		(44.8)	(224.7)	↑ (219.9)	(230.3)	↑ (226.3)	(369.8)	↑ (255.4)
Cash Position		1,290.8	971.4	↓ 969.6	783.7	↑ 784.7	484.9	↑ 582.5
EPS		(0.56)	(4.01)	↑ (3.86)	(4.06)	↑ (3.99)	(6.55)	↑ (4.49)
Valuation								
		2018A		2019E		2020E		2021E
P/Rev		17.3x		24.4x		21.7x		29.4x
EV/Rev		13.6x		19.1x		17.0x		23.0x
EV/EBIT		NM		NM		NM		NM
FY P/E		NM		NM		NM		NM

Reiterate Buy; Boost Price Target +8% to €130

Lead product filgotinib underpins the majority of our €130/share sum-of-the-parts valuation and remains the focus for investors. Gilead licensed global rights in December 2015 providing a partner to maximise the drug's commercial potential, after AbbVie elected to opt-out in favour of prioritising its own JAK inhibitor upadacitinib. We are encouraged by filgotinib's competitive profile based on the Phase IIb DARWIN and Phase III FINCH rheumatoid arthritis (RA) clinical data, with results from the Phase II FITZROY trial also suggesting the drug is effective for inflammatory bowel disease (IBD). We forecast $6bn global blockbuster potential largely comprising $3bn in RA. The pivotal programme for GLPG1690 for lung fibrosis (IPF) is underway, and could have significant commercial potential, with GLPG1205 in Phase II and GLPG3499 in Phase I for the same indication. GLPG1972 with partner Servier for osteoarthritis, and out-licensed MOR106 for atopic dermatitis could also be underappreciated Phase II assets, in our view. Numerous other pipeline programmes could also crystallise value, notably the Toledo programme, via possible milestones from existing alliances or new deals, and potentially drive positive share price momentum.

FINCH programme supports potentially differentiated safety profile for filgotinib

Selective JAK1 inhibitor filgotinib promises to be a safe and convenient oral treatment for rheumatoid arthritis (RA). Encouraging Phase II data in Crohn's disease (CD) suggest the drug could also have potential in IBD, perhaps a greater unmet medical need albeit a smaller eligible patient population. Multiple proof-of-concept studies in other indications are ongoing. Compared to currently approved biologic agents such as TNFs (e.g. Humira), filgotinib is administered orally, targets JAK1 specifically, and has a rapid onset, sustained response and potential for monotherapy use.

- **Peak sales forecast:** $6bn with $3bn in RA, $600m in CD, $400m in ulcerative colitis (UC), and a $2bn cumulative contribution for other indications
- **Valuation:** c.€85 per share with a 80% probability of success
- **Next news flow:** Possible update on US regulatory path for RA around mid-year, including potential MANTA male safety data timings, with EU and Japan filings during 2H19E; Phase II data in Sjogren's syndrome and cutaneous lupus erythematosus around 2H19E

MANTA could be the rate-limiting step for US filing

Recall FDA did not allow use of the highest 200mg/day filgotinib dose in US sites in the Phase IIb DARWIN trial on the basis of regulatory concerns on the male reproductive system based on rat/dog toxicology studies. Thus, FDA allowing inclusion of the 200 mg/day dose in the FINCH programme was an important positive, in our view. We understand the DARWIN trials confirmed no clinically meaningful changes in male hormone levels, including at the 200mg/day in ex-US patients.

The FINCH programme also includes a dedicated male patient testicular safety study, MANTA, which could finally lay safety concerns to rest, in our view. We note that a different FDA division approved the Phase III DIVERSITY study in CD and the Phase IIb/III SELECTION study in UC patients; for these trials, enrolled US males are only eligible to receive the higher 200mg/day dose if they have failed at least one prior biologic.

We understand the FDA recently allowed expansion of the inclusion criteria for MANTA, which has helped to accelerate enrollment. Meanwhile, Galapagos is leading the MANTA-RAy study (NCT03926195), evaluating semen parameters in patients with rheumatic diseases (RA, psoriatic arthritis, ankylosing spondylitis and non-radiographic

axial spondyloarthritis) and permitting a broader age range of 21 to 65 years (versus 25-55 years in MANTA). Results of both studies may be pooled, aiming for a total of c.250 patients across both studies, with 200 required by the FDA to assess sperm counts.

Whilst we expect European and Japanese filing during 2H19E, US filing timelines will depend on FDA discussions and whether it will be possible to file with the existing FINCH dataset, with results from the MANTA trial then submitted later. Once there is clarity from the FDA on the path forward, Gilead should update on timing for MANTA data if this is required for filing.

Broad applicability means multi-blockbuster potential

We forecast peak sales of $3bn in RA, $600m in CD and $400m in UC. We understand Gilead and Galapagos aim to pursue development of filgotinib in 10 to 14 indications, not including the Crohn's sub-populations. Given this extensive programme we include a $2bn WW peak sales contribution reflecting filgotinib's potential use in other indications beyond RA and IBD. We note Humira was not the first anti-TNFα biologic to be approved but it is now the most commercially successful, in part due to its regulatory approvals for numerous indications. Currently we believe 35%-40% of Humira's global sales are from its use in indications other than RA and IBD, hence we estimate a 30%-35% contribution from these diseases for filgotinib representing around $2bn at peak.

We estimate 20%-30% tiered royalties on sales to Galapagos from partner Gilead, but anticipate a 50:50 profit-share on co-promotion in EU5 and Benelux. Galapagos is still eligible to receive up to $1.27bn in milestones, of which $600m are dependent on achieving sales targets, and is responsible for funding 20% of R&D spend.

Hike Price Target +8% to €130

Our €130 per share Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for filgotinib, GLPG1690 in IPF, GLPG1972 in osteoarthritis, MOR106 in atopic dermatitis, the CF partnership, together with Net Cash.

Exhibit 1 - Galapagos Sum-of-the-Parts Valuation

	Indication	Peak Sales ($mn)	Value (EURmn)	Prob.	Adj. Value (EURmn)	EUR per share
filgotinib	RA, Crohn's, Ulcerative Colitis & Others	6,000	5,677	80%	4,542	83.2
CF Collaboration	Cystic fibrosis	2,000	908	15%	136	2.5
GLPG1690	Idiopathic pulmonary fibrosis	850	2,049	30%	615	11.3
GLPG1972	Osteoarthritis	3,000	1,453	20%	291	5.3
MOR106	Atopic dermatitis	1,500	675	30%	203	3.7
Net Cash/(Debt)			1,305	100%	1,305	23.9
Valuation			**12,068**		**7,091**	**129.8**
Potential Dilution for Funding	Min. Yrs of Cash	3.0		0%	0	0.0
Potential Diluted Valuation						**129.8**

Source: Jefferies estimates

Exhibit 2 - Galapagos Sources of Potential Upside and Downside Risks

	Upside	EUR per share	Downside	EUR per share
filgotinib regulatory filings in RA	Major filings in 2H19E	0.0	Delays or MANTA safety concerns	(67.6)
filgotinib Phase III in Crohn's & Ulcerative colitis	Positive data confirm profile	10.4	Efficacy and/or safety concerns	(15.6)
MOR106 Phase II IGUANA in atopic dermatitis	Positive efficacy & safety	2.5	Discontinued or delayed	(3.7)
GLPG1690 Phase III ISABELA in IPF	Positive efficacy & safety	18.8	Efficacy and/or safety concerns	(11.3)
Potential Upside/(Downside)		**31.6**		**(98.1)**
Potential Valuation		**161.5**		**31.7**

Source: Jefferies estimates