Notes from the Road: Filgotinib in Focus

16 April 2019

Key Takeaway

We hosted the Galapagos CMO in London where there was significant focus on filgotinib, in addition to IPF and Toledo. With efficacy comparable to other JAKis and best-in-class safety suggesting a superior risk:benefit profile, partner Gilead plans to meet with FDA in 2Q19 to explore the possibility of filing based on the existing FINCH dataset, with the MANTA Phase II male safety potentially to be submitted later. Please call us for more details.

FINCH data position filgotinib well in Rheumatoid Arthritis (RA)

Efficacy data from the three Phase III FINCH trials in RA suggest that filgotinib's efficacy is similar to key competitor upadacitinib. Management noted that on an absolute basis the ACR20/50/70 scores are higher with filgotinib, but broadly comparable on ACR50/70 when adjusted for placebo, with the latter more important for clinicians, in addition to clinical remission. High placebo rates were speculated as owing to the geographic location of some of the trials (Eastern Europe and India) in addition to "class creep" whereby patient expectations around efficacy for later entrants in a class can positively bias placebo response rates. 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.

Best in class safety might allow for US filing on existing data

With comparable efficacy and best in class safety, avoiding the typical thrombotic events associated with the JAKi class, management and partner Gilead believe filgotinib has a better risk:benefit profile than other JAKi. A meeting with the US FDA has been requested 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 leading an effort to expand MANTA to include rheumatic diseases and broader inclusion/ exclusion criteria, seeking to enrol a total of c.500 patients, with 200 required by the FDA to assess sperm counts.

Renewed interest in filgotinib combinations under new Gilead CEO

Gilead's new CEO Daniel O'Day visited Galapagos within a month of taking the helm. There is now renewed interest in filgotinib combinations, including with BTK inhibitors. Separately, management noted that the development spend cap on the 20% of R&D costs that GLPG co-funds is "within sight".

IPF could be the first go-it-alone indication for Galapagos

The Phase III ISABELA programme evaluating GLPG1690 in lung fibrosis (IPF) is ongoing with 230 sites globally to enrol 1,500 patients. Recruitment is estimated to take around 24 months, implying data potentially 1H22E, with management expecting to provide an update in 3Q19E. The trial includes a futility analysis when 25% of patients have completed 12 months of treatment.

Secret Toledo target could be disclosed within 9-12 months

The target of the Toledo compounds will remain undisclosed until Phase II trials are initiated, with the first of a series of Phase II trials that may run in parallel potentially

FLASH NOTE	
RATING	BUY
TICKER	GLPG NA
PRICE	€108.95^
PRICE TARGET (PT)	€120.00
MARKET CAP	€5.9B / $6.7B

RATING	BUY
TICKER	GLPG
PRICE	$122.10^
PRICE TARGET (PT)	$136.00
MARKET CAP	€5.9B / $6.7B

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

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commencing by YE19/1Q20 in IBD. Phase I data for GLPG3312 are expected in 2H19E.

Company Description

Galapagos

Galapagos is a Belgian biotech company focusing on drug discovery using cells taken from patients with diseases of interest; typically musculoskeletal, CNS and inflammatory disorders plus orphan indications. The company's most advanced product is filgotinib (GLPG0634 a JAK1 inhibitor) is in Phase III for rheumatoid arthritis, Crohn's disease and ulcerative colitis partnered with Gilead. Galapagos also has a global alliance with AbbVie in cystic fibrosis. The company also has active collaborations with Servier and MorphoSys.

Company Valuation/Risks

Galapagos

Our Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for filgotinib, the cystic fibrosis alliance, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and MOR106 in atopic dermatitis, plus Net Cash. Risks include: (1) efficacy, safety, or regulatory setbacks; (2) need to execute future out-licensing and alliances; and (3) clinical trial failures.

Gilead Sciences, Inc.

Our $95 PT is based on a pipeline-adjusted DCF and 16x our 2019 EPS estimate. Risks: competition, pipeline disappointments, and worse-than-expected sales.

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(Article 3(1)e and Article 7 of MAR)

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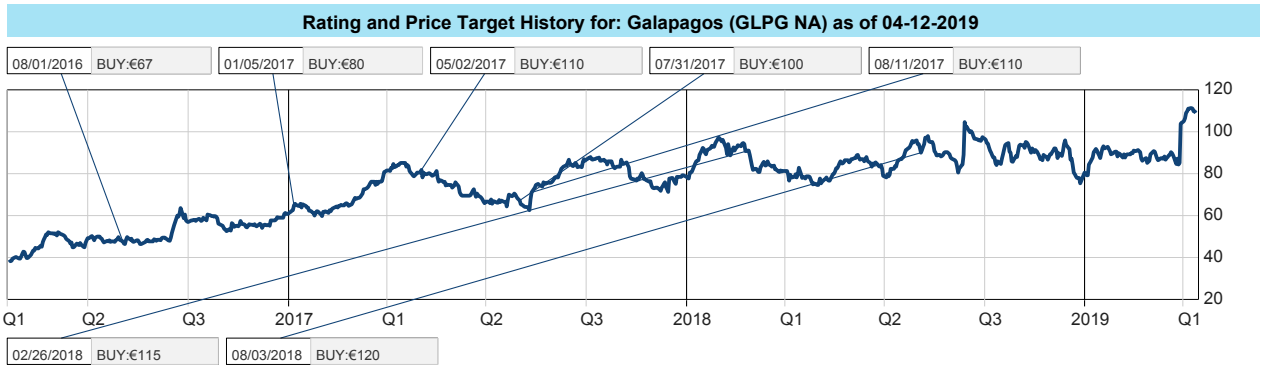

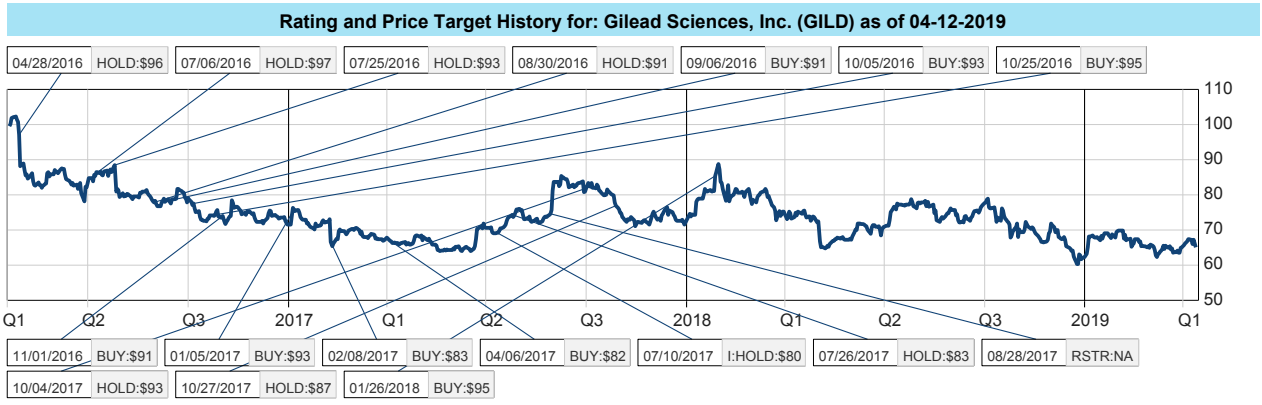

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H: Hold

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Distribution of Ratings						
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HOLD	811	38.44%	10	1.23%	1	0.12%
UNDERPERFORM	144	6.82%	1	0.69%	0	0.00%

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