Galapagos

Ball's in FDA's Court with US Filgotinib Filing Now Confirmed for 2019

2 July 2019

Key Takeaway

Partner Gilead's intention to submit a US NDA for filgotinib this year is welcome, suggesting FDA is amenable to a filing based on the totality of the data package to-date, removing uncertainty for the stock, in our view. Filgotinib's impressive safety profile could be an important differentiator, potentially key to driving uptake despite likely being the 4th JAKi to market. It remains unclear whether MANTA male toxicity data will be required for filing. Buy.

US filgotinib filing confirmed for 2019: Following a planned meeting with FDA to discuss the totality of the existing filgotinib dataset, partner Gilead has confirmed that a "path forward" to US NDA filing has been established, allowing submission in 2019. The specific FDA requirements regarding data from the Phase II MANTA male safety trial have not been outlined, nor have timings for the availability of data from MANTA. Nevertheless, this is a positive outcome, as it appears that full MANTA data may now not be a rate limiting step for filing. We continue to expect regulatory filings in Europe and Japan in 3Q and 4Q19E, respectively.

Filgotinib FINCH data suggests potentially differentiated safety profile: Efficacy data from the 3 Phase III FINCH trials in RA suggest filgotinib's efficacy is similar to key competitor upadacitinib. On a 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.

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 an 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 gaining attention with focus on secret Toledo: GLPG plans to start a Phase II with the 1st gen Toledo compound GLPG3312 in ulcerative colitis by YE19/1Q20. This is despite undisclosed toxicity with '3312 that prevents oral systemic delivery. As the target is likely to be revealed upon Phase II initiation, management is keen to maintain its development timeline advantage. 2nd gen compound '3970 could be better tolerated, which, if confirmed in Phase I, would then be developed across multiple parallel Phase II trials across a broad range of inflammatory diseases from 2020E. The Nov R&D day will highlight Toledo. GLPG1690 is in the Phase III ISABELA programme in lung fibrosis (IPF) and a Phase II in systemic sclerosis. The Phase IIb ROCELLA trial of GLPG1972 in osteoarthritis recently completed recruitment ahead of schedule, for data by YE20E.

FLASH NOTE	
RATING	BUY
TICKER	GLPG NA
PRICE	€114.60^
PRICE TARGET (PT)	€130.00
MARKET CAP	€6.3B / $7.1B

RATING	BUY
TICKER	GLPG
PRICE	$130.44^
PRICE TARGET (PT)	$145.00
MARKET CAP	€6.3B / $7.1B

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

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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 PT is based on a pipeline-adjusted DCF and multiple of 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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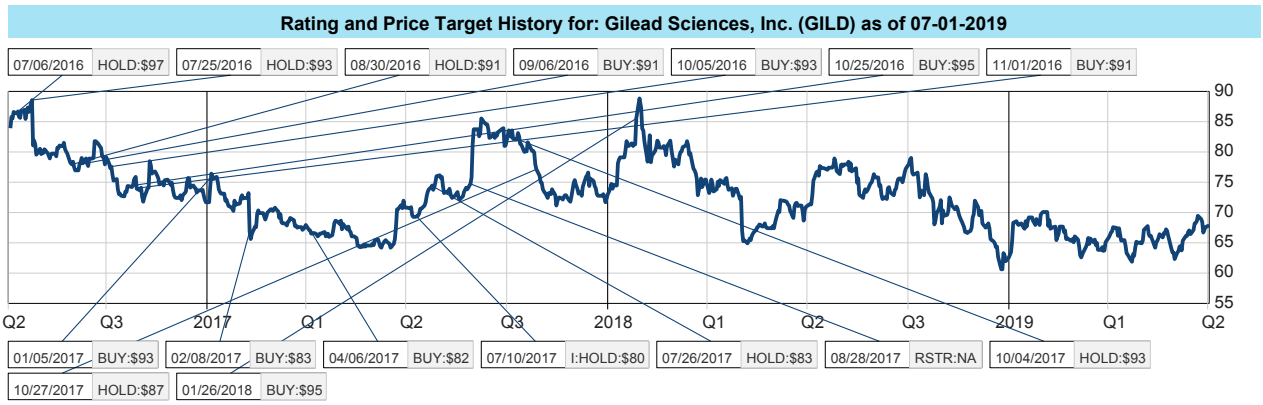

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D: Dropped Coverage

B: Buy

H: Hold

UP: Underperform

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Distribution of Ratings						
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BUY	1165	54.54%	92	7.90%	14	1.20%
HOLD	831	38.90%	18	2.17%	3	0.36%
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