March 28, 2019

OUTPERFORM

Reason for report:

FLASH NOTE

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GALAPAGOS NV

The JAK inhibitor that got away: Filgotinib shines

• **Bottom Line:**Galapagos and collaborative partner Gilead (GILD/MP) announced Phase 3 data from FINCH1 and FINCH 3 showing filgotinib is safe, effective with clear dose response in patients with rheumatoid arthritis (RA). Both trials met the primary efficacy endpoint. At both doses tested (200 mg and 100 mg), filgotinib showed an improved safety profile versus other JAK inhibitors, especially highlighting reduced rates of Herpes zoster infection compared to other inhibitors tested to date and background, low rates of deep vein thrombosis (DVT) and pulmonary embolism (PE). Filgotinib performance as profiled by these large registrational trials could potentially make this drug the poster child for JAK inhibitors, as they were intended to perform, but have fallen short due to lack of dose response, poor safety profiles and incremental real world efficacy.

• **Safety is key, and filgotinib stands apart.** Herpes zoster infections and DVT/PEs have been dragging the field down. Aggregated safety data across all three FINCH trials showed Herpes zoster infections occurred in 12/2088 (0.6%) of patients treated with filgotinib which was similar to infection rates seen in patients treated with placebo plus csDMARD (4/1039, 0.4%) and patients treated with adalimumab plus MTX (2/325, 0.6%). DVT/PE rates for patients treated with filgotinib (1/2088, <0.1%) were below that seen in patients treated with placebo plus csDMARD (2/1039, 0.2%), while patients treated with adalimumab plus MTX did not have any DVT/PE events. These findings are an improvement over other JAK inhibitors which have shown a high rate of Zoster infections as well as more DVT/PEs events. While we expect that all medicines that modulate the immune system will have some adverse events, the higher rates of infectious complications and the surprise cardiovascular saga associated with baricitinib and tofacitinib have cast a shadow over the whole field. While we are confident that the differences in Herpes zoster infection are likely real based on the differential impact of filgotinib on Natural Killer cell activity, we are hopeful that the low DVT/PE rates will hold as the patient-year experience accumulates for filgotinib. Given the as of yet unknown etiology of JAK inhibitor induced DVT/PE's, while reassured, we cannot be certain that filgotinib is home free on this safety dimension. While there is some speculation that this may be a class effect, the JAK inhibitors don't necessarily follow the classic classification for class effect and therefore caution needs to applied.

• **Filgotinib is dose responsive.** Filgotinib met the primary efficacy endpoint in both FINCH 1 and FINCH 3 at both the 200 and 100 mg doses. Physicians as of yet do not have a safe and effective, dose responsive option for an oral therapy. Looking ahead to a potential filing, this dose responsiveness, without increased safety overhang, gives GILD/GLPG a rare opportunity to provide physicians and patients with a clear benefit-risk mitigated treatment strategy. Upadacitinib's lack of clear separation on efficacy (ACR20) between the 15 and 30 mg doses in SELECT-BEYOND, has limited the potential optionality for approval.

• **Filgotinib meets primary efficacy endpoint.** FINCH 1 was a 24 week study conducted in 1755 moderate-to-severe RA patients with an inadequate response to methotrexate (MTX). Patients were

Key Stats: **(NASDAQ: GLPG)**

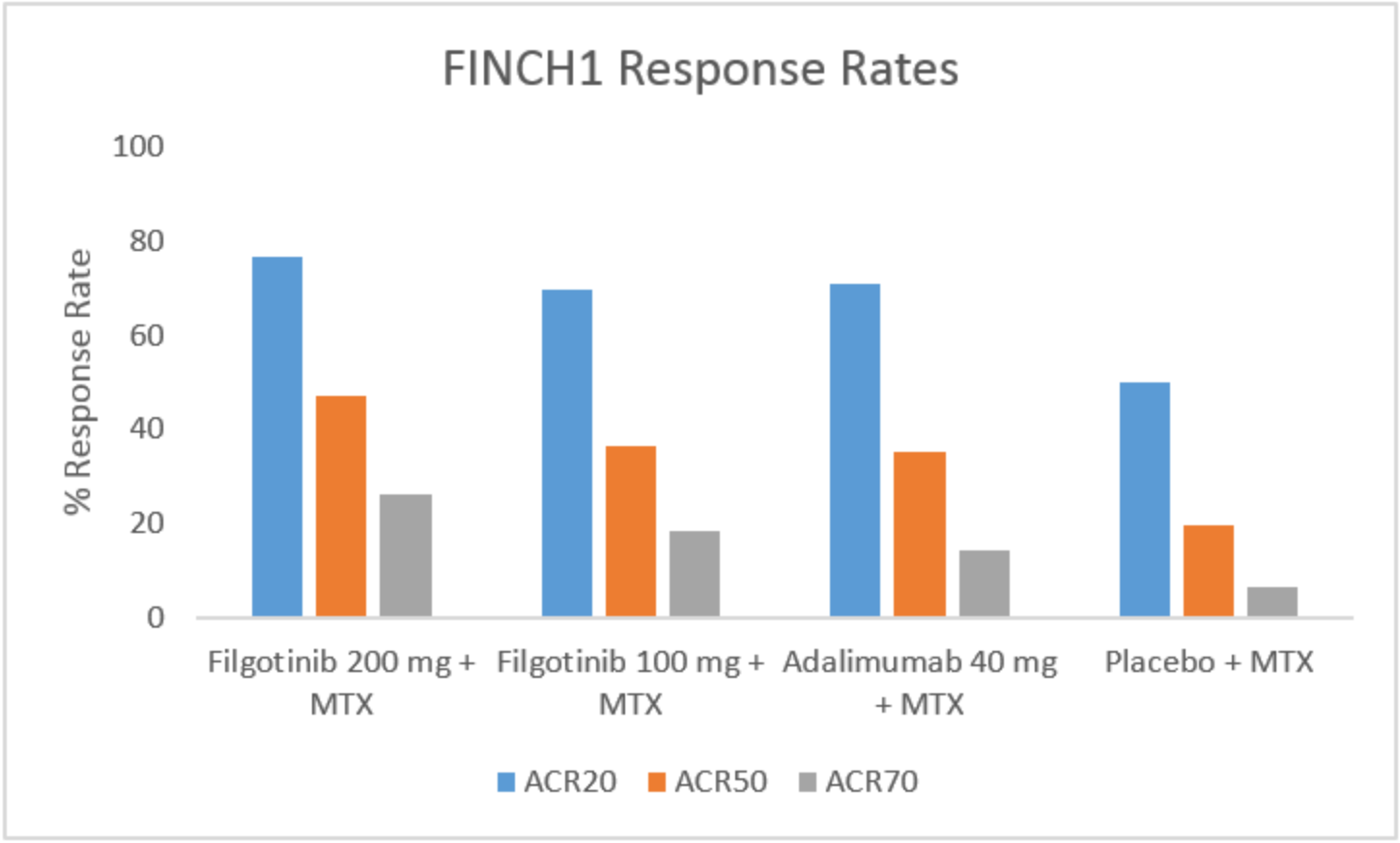
Sector:	**Biopharma / Immunology & Metabolism**
S&P 500 Health Care Index:	**1,050.07**
Price :	**€96.13**
52 Week High:	€122.28
52 Week Low:	€85.00
Shares Outstanding (mil):	54.4
Market Capitalization (mil):	$5,229.5

Completion: March 28, 2019, 11:26PM EDT.
Distribution: March 28, 2019, 11:26PM EDT.

given 200 mg filgotinib plus MTX (n=475), 100 mg filgotinib plus MTX (n=480), 40 mg adalimumab plus MTX (n=325), or MTX alone (n=475). Patients treated with either dose of filgotinib showed a significant difference in ACR20/50/70 response rates (high dose 76.6%/47.2%/36.3%, low dose 69.8%/36.3%/18.5%) versus MTX alone (49.9%/19.8%/6.7%). However, the low dose was in line with adalimumab plus MTX (70.8%/35.1%/14.2%). FINCH 3 was a 24 week study conducted in 1249 moderate-to-severe RA patients naïve to MTX. Patients were given 200 mg filgotinib plus MTX (n=416), 100 mg filgotinib plus MTX (n=207), 200 mg filgotinib monotherapy (n=210) or MTX monotherapy (n=416). Patients treated with both doses of filgotinib plus MTX showed a significant difference in ACR20/50/70 response rates (high dose 81.0%/61.5%/43.8%, low dose 80.2%/57.0%/40.1%) versus MTX alone (71.4%/45.7%/26.0%). Filgotinib monotherapy (78.1%/58.1%/40.0%) only showed a significant difference for ACR50 and ACR70 response rates. Response rates were largely in line with response rates observed for upadacitinib in trials conducted in similar patient demographics.

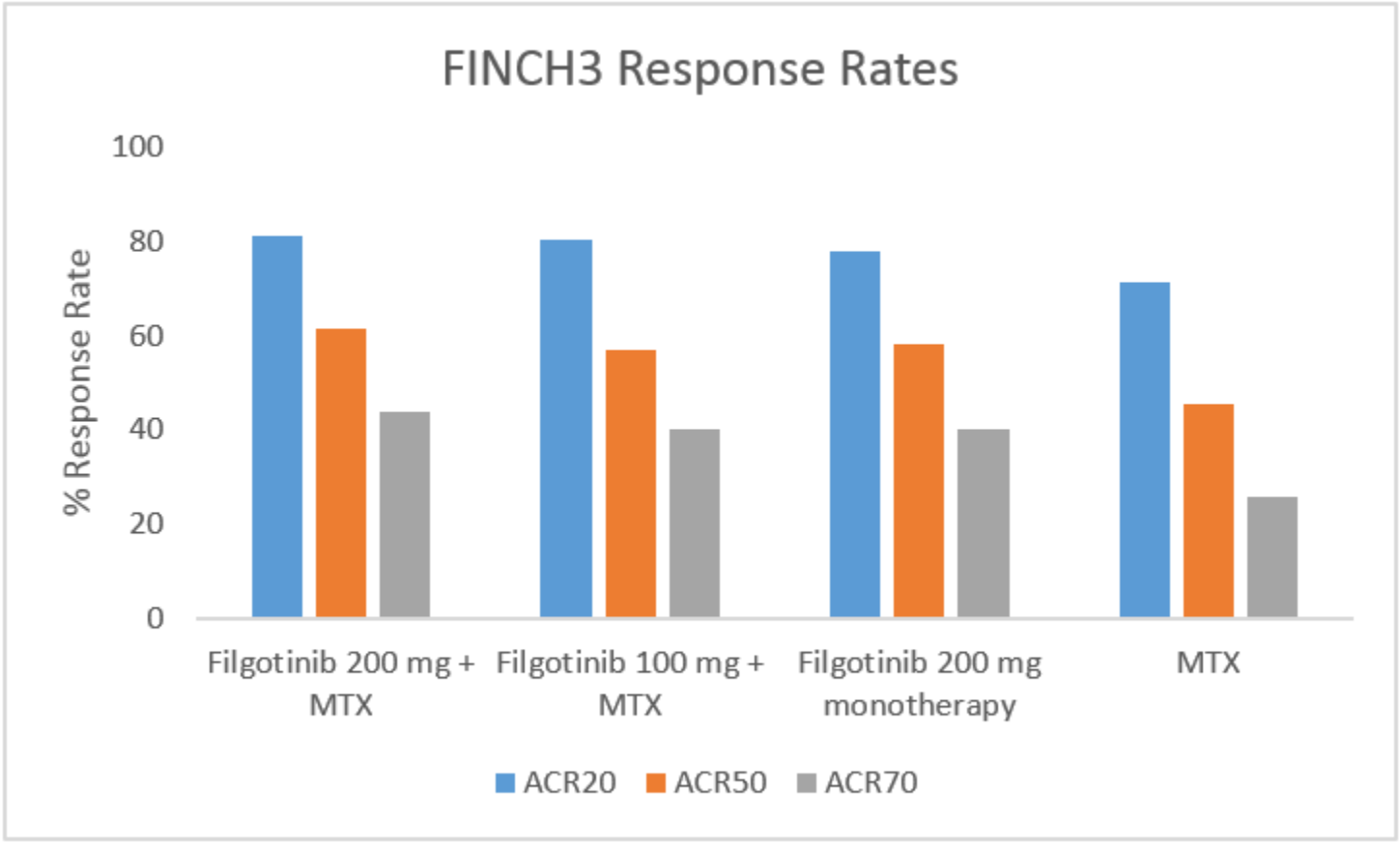
• **Results a strong positive for GLPG.** We had previously indicated positive results suggested $10/share upside to our valuation (see HERE). Our valuation assumes a market launch in 2H20 with no or minimal delay caused by a readout for the MANTA trial. We continue to view the testicular toxicity that appeared in preclinical trials as a minor risk factor for filgotinib's given prior precedent set by other commercial stage drugs that have also displayed a history of testicular toxicity in pre-clinical, clinical or real world settings (see HERE). These FINCH results for filgotinib indicate a potential to file an NDA at both the 100 mg and 200 mg dose. We view both doses as being critical to differentiating filgotinib in the market and unlocking its full value potential. GLPG is eligible to receive about $685M in developmental and regulatory milestones and $600M in commercial milestones from GILD, will assume 35% of co-promotional efforts in Germany, France, Italy, Spain, the UK, Belgium, Luxembourg and the Netherlands, and is eligible to receive between 20%-30% in royalties on all commercial sales outside of these regions.

Phase 3 FINCH 1 Results



Source: Company releases and SVB Leerink Research

Phase 3 FINCH 3 Results



Source: Company releases and SVB Leerink Research

Aggregated Safety Data From FINCH1, FINCH2 and FINCH3

	Placebo/ csDMARD N= 1039 No. (%)	Adalimumab + MTX 40mg EOW N=325 No. (%)	Filgotinib 100 mg +MTX/csDMARD N=840 No. (%)	Filgotinib 200 mg +MTX/csDMARD N=1038 No. (%)	Filgotinib 200 mg N=210 No. (%)	Filgotinib Total N=2088 No. (%)
Serious infections[&]	10 (1.0)	8 (2.5)	13 (1.5)	13 (1.3)	3 (1.4)	29 (1.4)
Herpes zoster[&]	4 (0.4)	2 (0.6)	5 (0.6)	6 (0.6)	1 (0.5)	12 (0.6)
DVT/PE[&]	3 (0.3)	0 (0)	0 (0)	1 (0.1)[μ]	0 (0)	1 (<0.1)
Death[@]	2 (0.2)	0 (0)	1 (0.1)	3 (0.3)	0 (0)	4 (0.2)
Malignancy excluding NMSC[&]	4 (0.4)	1 (0.3)	1 (0.1)	0 (0)	0 (0)	1 (<0.1)
MACE[&]	5 (0.5)	1 (0.3)	2 (0.2)	2 (0.2)	1 (0.5)	5 (0.2)

Source: Company releases and SVB Leerink Research

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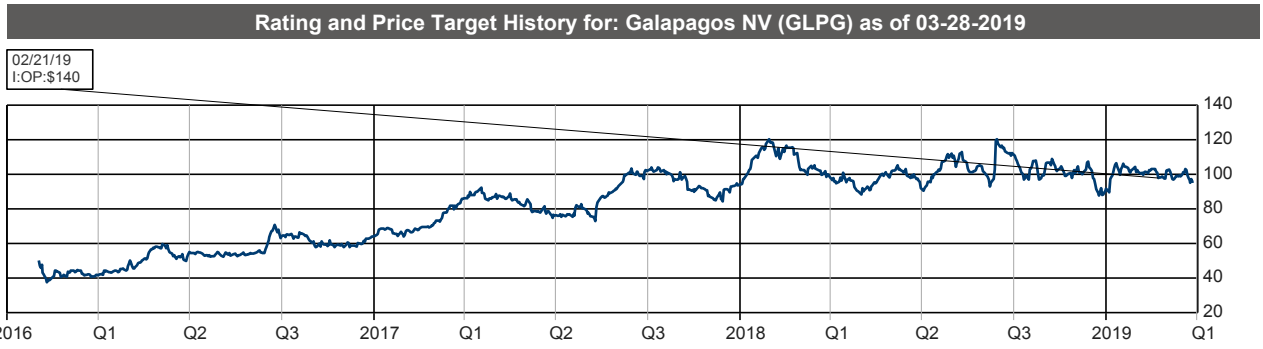
Disclosures Appendix

Analyst Certification

I, Pasha Sarraf, M.D., Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.



OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

Created by: BlueMatrix

Valuation

Our $140 PT was determined using a Sum of the parts valuation that applied a WACC calculated 11.9% discount rate and 2% terminal growth rate to revenues and cash flows projected into 2028. Revenues for each asset were adjusted independently twice: by probability of regulatory approval, and by asset specific commercial profile.

A commercial probability distribution was determined based on a revenue weighted distribution of independent commercial scenarios projected for each drug candidate. GLPG1690 and filgotinib comprise a majority of the valuation. Galapagos held €1.3B in cash and cash equivalents as of the end of 4Q18. Pro forma cash was not applied to this valuation.

Risks to Valuation

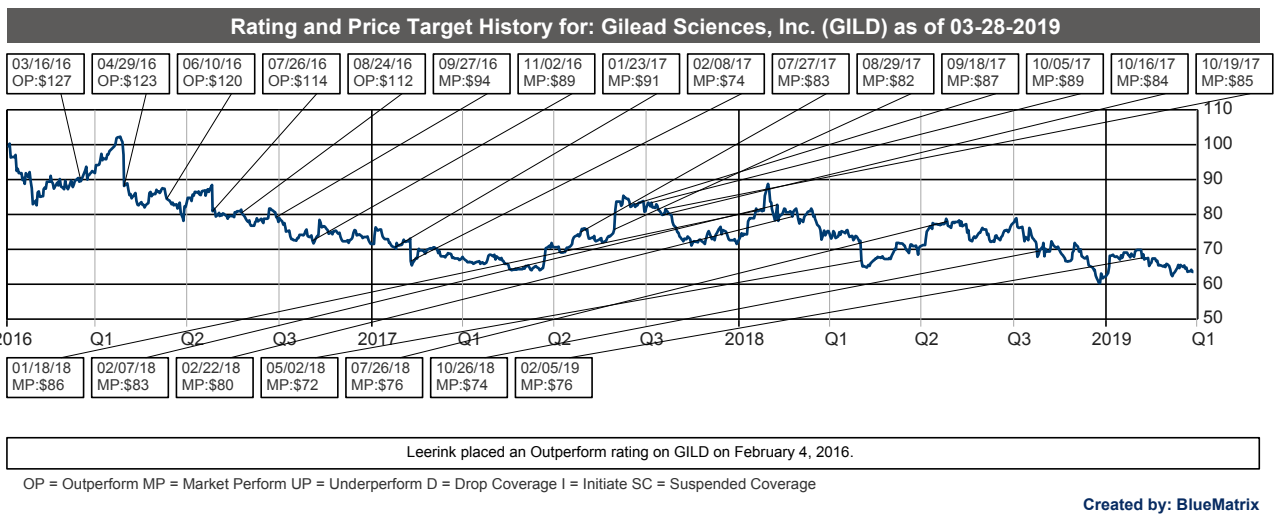
Risks to Valuation include the following:

Product Risk - One or more of the clinical trials for filgotinib or GLPG1690 may fail to meet its primary endpoint necessitating a deeper decision into continued development in that particular indication. Additionally, any safety issues that occur within one trial for filgotinib may read negatively across the entire filgotinib franchise.

Collaboration Risk - Multiple products within GLPGs pipeline, including filgotinib and MOR106 are being developed and will be marketed away from GLPG's control. This gives GLPG limited ability to address situational issues surrounding the success of these drugs.

Regulatory Risk - The FDA has previously indicated a belief in drug combinations as the likely future for IPF treatment. With this in mind, GLPG has pursued pivotal trial investigating GLPG1690 in combination with standard of care. While we believe this creates a safer path to approval, it nonetheless opens the door to potential competitors pursuing a path to approval as a monotherapy to significantly disrupt expectations for market competition

Financing Risk - GLPG currently has no revenue producing products on the market. Though well capitalized over the near term, negative outcomes for any of their asset franchises may significantly impact their ability raise funds in the future.



Valuation

Our $76 price target for Gilead Sciences, Inc. (GILD) is based on an average of four approaches that we believe are a reasonable basis for valuing the stock today. These approaches are trough price to earnings multiples for large cap, slow-growth medical products businesses long term; revenue multiples for large cap biopharma products stocks with slow growth outlooks; sum of the parts valuation for existing franchises; and discounted cash flow (DCF). Using a trough consensus forward earnings (2019E) multiple for slow-growth medical products stocks (AGN, ABBV, CELG, BIIB, AMGN) of 11.7x, applied to our 2020E EPS estimate for Gilead, gives a price of $77. Alternatively we apply an ex-growth large-cap medical products (BIIB, ABBV, AMGN, BMY, MRK, PFE, MRK, AZN, GSK, NVS) revenue multiple (4.3x) to 2020E revenue estimates to derive an implied value of $93bn, implying a one year price target of $72. Using a sum of the parts valuation for existing franchises, we get a price of ~$83, consisting primarily of a price of ~$63 for the company's HIV franchise. Lastly, our DCF uses our forecast of free cash flow through 2029E and then applies a -4% growth rate to our terminal cash flow forecast and discounts the values back to the present at a 7.9% WACC to give a present value of $72. The average of these four approaches is $76, which is our price target.

Risks to Valuation

The risks to our view, outlook, and valuation for Gilead include any major change in the labeling, price, or reimbursement coverage for the company’s existing HIV or HCV products, emergence of further aggressive price discounting, rebating, or other value erosion in the HIV and HCV categories, over and above our current forecast, or any failure of the company’s principal pipeline assets, selonsertib (NASH) and filgotinib (RA, IBD) to advance through development to commercialization. Opportunities for better performance and value than our expectations include delays or limitations in the development, profile, and adoption of competitive HIV products, successful development of underappreciated elements of the company’s portfolio, such as selonsertib (ASK-1 inhibitor) GS-9674 (FXR agonist), GS-0976 (ACC Inhibitor), or follow-on CAR-T indications and stronger-than-expected conversion of current HIV patients to Gilead’s next generation TAF-based HIV treatment regimens.

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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/18				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	142	71.4	51	35.9
HOLD [MP]	54	27.1	2	3.7
SELL [UP]	3	1.5	0	0.0

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.

The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

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Important Disclosures

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SVB Leerink LLC makes a market in Galapagos NV and Gilead Sciences, Inc.

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