

August 18, 2019

OUTPERFORM

Reason for report:

COMPANY UPDATE

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GALAPAGOS NV

Safety Uncertainty Forces FDA's Hand on JAK Inhibitors

• **Bottom Line:** We believe the broad labeling for thrombosis risk on the upadacitinib label is likely to limit the overall market size for JAK inhibitors.

• **Broad labeling for JAK inhibitors.** The inclusion and wording of a black box warning for thrombosis and embolism risk in the label for upadacitinib are now likely to be applied across all JAK inhibitors used for autoimmune diseases. We have spoken to GLPG management who believe that they can make a case based on their differentiated adverse event (AE) rates to avoid such language. Other regulatory specialists we have contacted over the weekend, however, believe it is unlikely that filgotinib or other JAK inhibitors will be able to avoid such labels in the future. The proof of absence is hard to make in the real world, requiring enormous numbers of patient-years of exposure, which may be just as likely to increase the rates as decrease them, as we have seen with Xeljanz. In the view of these specialists, given the time needed to accumulate these numbers, together with the significant uncertainty around the occurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE) events, the FDA is unlikely to spare future JAK inhibitors with a "clean" label. We view this as a prudent approach by the FDA given the danger of thrombotic events as silent killers. Furthermore, the mechanism of why these events are occurring is unclear. During baricitinib's advisory committee both the FDA specialists and Eli Lilly attempted to explain the potential mechanisms for why these events could occur mechanistically via inhibition of the JAK pathways, but in our view came up short, with the FDA providing what we saw as an unlikely rationale for thrombotic events and Eli Lilly rebutting with a corporatized response that we saw as short of compelling, as suggested by the outcome. The scientific literature does not offer adequate explanations for why JAK inhibitors may or may not be driving increased thrombotic events, nor have other players with active programs, including GLPG, offered meaningful hypotheses on what's going on. In effect there is a scientific and clinical vacuum. In this vacuum, the FDA has chosen to be careful with caution to physicians. The clinical trialists we spoke with do not pay any attention to these type of warnings, but note that general practitioners do. According to those specialists, however, the details of the adverse events tables are important and may drive their choices for prescribing. The ability to share this data may provide some ability for differentiation. We believe this safety overhang, on top of expected and well-known concerns such as heightened infection risk and those of malignancy, will negatively impact the breadth and speed of JAK inhibitor uptake in the treatment of rheumatoid arthritis (RA) despite the need for better treatments in the space.

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Key Stats:

(NASDAQ: GLPG)

Sector: Biopharma / Immunology & Metabolism
S&P 500 Health Care Index: 1,045.87
Price: €172.18
Price Target: \$200.00
Methodology: SOTP with WACC-calculated 11.9% discount rate and a 2% terminal growth rate to the discounted cash flow value of each asset. DCF values were adjusted by asset specific probability of regulatory success.

52 Week High: €191.63
 52 Week Low: €85.00
 Shares Outstanding (mil): 61.7
 Market Capitalization (mil): \$10,623.5
 Cash Per Share: \$97.60
 Dividend (ann): €0.00
 Dividend Yield: 0.0%

Completion: August 18, 2019, 8:48PM EDT.
 Distribution: August 18, 2019, 8:48PM EDT.
Price: Intra-day price



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2018A	€44.8	€57.0	€103.2	€112.8	€317.8	(€0.73)	(€0.42)	€0.29	€0.28	(€0.56)	NM
2019E	€40.9A	€67.6A	€220.4	€316.6	€645.5	(€0.89)A	(€0.86)A	€1.73	€3.19	€3.63	47.4x
2020E	€105.4	€105.5	€236.0	€197.2	€644.1	(€0.33)	(€0.42)	€1.56	€0.81	€1.66	NM

Source: Company Information and SVB Leerink LLC Research.
Revs in €MM; EPS diluted non-GAAP

INVESTMENT THESIS

Filgotinib's superior safety profile versus other JAKi's makes it a potentially best-in-class JAKi that has an opportunity to compete with anti-TNF agents in rheumatoid arthritis (RA) and inflammatory bowel disease (IBD). We believe GLPG has a potential best-in-care drug in GLPG1690 that has the potential to become the standard of care in IPF treatment. With limited effective treatments in IPF, GLPG1690 carries blockbuster potential but with a projected 2023 market launch. While we view gaining approval to treat osteoarthritis (OA) highly unlikely given the history of clinical efforts, we cannot ignore the massive opportunity should GLPG1972 gain regulatory approval.

The research and development collaboration with GILD provides significant upfront cash for the promise of future development. We expect GLPG's proprietary discovery platform to continue to produce uniquely profiled drugs that will keep the doors open and the partnership productive.

VALUATION

Our \$200 PT was determined using a probability weighted scenario analysis. Individual scenario values were determined by 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 €1.1B in cash and cash equivalents as of the end of 2Q19 but received ~\$5.1B in the R&D collaboration agreement in early 3Q19. Pro forma cash is included in 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 its asset franchises may significantly impact its ability raise funds in the future.

Downside impact on GLPG 12-month PT buffered by Gilead. While we see filgotinib as receiving a similar treatment by the FDA, GLPG is somewhat protected from the downside impact. First, GLPG is receiving 20% to 30% tiered royalties on U.S. sales of filgotinib, which serves to blunt the economic impact of changes in U.S. sales projections for filgotinib. Reducing our projected U.S. sales for filgotinib in RA by 25% would result in only a 2.5% decrease in our 12-month price target from \$200 to \$195 per share. Second, we estimate GLPG is yet to receive ~\$1.1B in regulatory and commercial milestones for filgotinib which helps to offset any decrease in potential royalties (these royalties are currently probability adjusted so assuming 100% probability they are received would increase our price target by ~2%). Finally, despite the inclusion of a significant warning on the U.S. FDA approved label, it is unclear if a similar warning will accompany labeling in the E.U., where GLPG will contribute and receive 50% of the economics for commercial efforts.

Walking through the scenarios. We performed a number of sensitivities for filgotinib following the upadacitinib's approval. Our best case scenario assumes filgotinib receives a differentiated label on safety which does not include thrombosis and embolism risk and is indicated for use in patients not responding to methotrexate. Here, we project filgotinib leading the JAK inhibitors with \$1.3B peak U.S. sales in RA in 2028, resulting in a 12-month price target of \$205 per share. Our base scenario assumes thrombosis and embolism risk are included in a black box warning with filgotinib indicated for use in patients not responding to methotrexate, with \$870M projected in peak U.S. revenue for filgotinib in RA and a 12-month price target of \$200 per share. A third scenario assumes filgotinib receives a differentiated label on safety, but is indicated for use in patients not responding or intolerant to biologics. This results in \$770M in U.S. sales in RA and a 12-month PT of \$197 per share for GLPG. A fourth and most bearish scenario assumes filgotinib receives an undifferentiated safety label that includes thrombosis and embolism risk, while also being indicated for use in patients not responding to biologics. This results in \$660M in projected peak U.S. sales in RA in 2028 and a \$195 PT. We believe scenario 2 (base case) is the most likely scenario with a 75% probability vs 10% probability for scenario 1, 10% probability for scenario 3, and 5% probability for scenario 4, leading us to maintain our current \$200 PT. Using our most bearish scenario for filgotinib in RA while simultaneously decreasing the peak size of the JAK market in ulcerative colitis (UC) and Crohn's disease (CD) by 30% results in a 7.5% downside risk to our current price target, or \$188 per share. While we believe this overall scenario across all indications is unlikely, we also recognize that our original estimates for the size of the JAK market as well as filgotinib's share of that market lean towards being conservative. This raises our confidence in maintaining our current \$200 PT