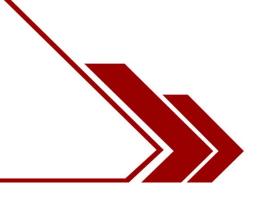


## Galapagos NV GLPG.OQ GLPG US

**EQUITY: AMERICAS BIOTECHNOLOGY** 



## Filgo Competitor Updates – PFE, LLY, INCY

# **Quick Note**

Today, GLPG competitors PFE, INCY, and LLY reported 1Q earnings, with material updates to their JAK franchise. With recent competitor updates, GILD/GLPG's filgotinib is likely to be the **only Jak inhibitor with both doses** on the market, pending approval (NDA filing 2H19). We believe that this bodes well for filgotinib's competitive profile as a pipeline in an asset within an increasingly large autoimmune market (<u>note</u>), with plenty of headroom for efficacy/safety improvements, and that it has recently been hit with cost-saving TNF biosimilars.

- PFE Posts Strong 1Q Volume Growth Despite Post-Marketing Low-Dose Switch, UC A Driver. Xeljanz was up 34% YoY operationally, driven by 89% operational growth in international markets. Though U.S. growth was up only 18%, we note there was a 37% increase in prescription count, offset by seasonally weak 1Q due to higher rebating and channel mix. All patients on 10mg BID have been translated to 5mg BID, based on mortality/PE imbalance found by DSMB in a post-marketing study (note). On the call, PFE noted "very strong market shares for UC . . . coming out of the gate," reinforcing our thesis that IBD remains a lucrative market opportunity with high demand for efficacious oral therapies.
- LLY Cancels P3 PsA Development Plans for Bari. P3 plans for Olumiant (baricitinib, JAK1/JAK2 inhibitor) in PsA was canceled, potentially indicating baricitinib's weak competitive profile in light of recent filgo data. On the call, LLY noted that the decision was made after looking at the market opportunity, then pointed to Taltz as its flagship product in this indication. However, we believe filgotinib's P2 results in PsA (note) on top of recent P3 filgo results contributed to this decision. In addition, LLY stated that the uptake of the low 2mg dose in the U.S. is slow and steady despite robust launch ROW with both doses, indicating the importance of dose optionality in the market place.
- INCY Ends Co-Funding Agreement for Baricitinib. Today, INCY announced the termination of co-funding agreement for baricitinib, which funded 30% of post-POC studies for an additional 9% royalties on top of 11-20%), to reallocate resources to its internal late-stage pipeline. We believe that this is a positive indicator that Olumiant remains a weaker filgo competitor vs. Upa.
- Next Up: Upa ADCOMM, Doses, VTE Rates. We expect Upa ADCOM
   (estimated in 3Q) to be key catalyst for GLPG, highlighting the relative
   safety profile, FDA concerns, and views on class-based SAEs (DVT/PE).
   FINCH studies had only one serious thromboembolic event in all filgo
   arms or 0.1 per 100 PYE vs. bari and Upa, which had VTE rates of 0.5 per
   100 PYE.

#### Instinet, LLC, Equity Research

#### 30 April 2019

Rating Remains	Buy				
Target Price Remains	USD 140.00				
Closing price 29 April 2019	USD 113.85				

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# **Appendix A-1**

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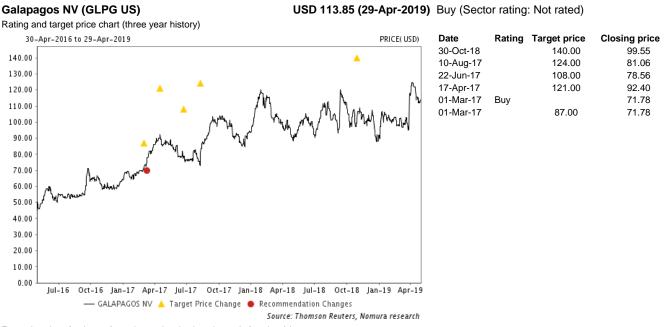
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suer Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
pagos NV GLPG US	USD 113.85	29-Apr-2019	Buy	Not rated	A4,A5,A6,A7

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For explanation of ratings refer to the stock rating keys located after chart(s)

**Valuation Methodology** Our target price of \$140 for Galapagos NV (GLPG) is based on an SOTP analysis, applying a 16x royalty multiple on peak filgotinib U.S. royalties and 6x multiple on peak filgotinib EU profits in 2025E (in RA, PsA, UC, and Crohn's), and an 8x orphan drug multiple on our peak sales estimate of GLPG1690 in IPF (2025E), discounted back to 4Q19E. We estimate filgotinib peak sales of \$6bn in 2025. In filgotinib for RA, we apply a 20% discount rate, reflecting a lower development risk with FINCH 2 readout, and as the target, JAK, is already validated by an approved drug in RA. For filgotinib in UC and Crohn's, we apply a 30% discount rate, reflecting a slightly higher risk for these indications and clinical stage. For filgotinib in PsA, we apply a 40% discount rate, reflecting the P2 clinical stage. For the IPF program, we use an 8x multiple, reflecting a higher value for the higher-margin orphan program and a 40% discount that reflects a higher development risk. The benchmark for this stock is the Nasdaq Biotechnology Index.

Risks that may impede the achievement of the target price Regulatory risk: For filgotinib, the FDA may issue a class label on the risk for serious infections and malignancies. This action will not prevent filgotinib from reaching the market, but it could create a negative perception of the drug among patients and physicians, which would affect commercial sales in a saturated market. Competitive risk: A superior oral agent achieves POC or enters market. If Upadacitinib gets approved without black-box label, it could take lion's share of the market. Competing IPF pipeline agents may achieve a speedier path to approval. Clinical

risk: The Phase 2 study with filgotinib in CD used the CDAI as the primary outcome measure. The Phase 3 study is using the more traditional PRO as the primary outcome measure. This difference in design may result in a smaller efficacy difference between the placebo and treatment arms in the Phase 3 study. Enrollment of patients in studies might take longer than anticipated. Safety signals compromising the compound's therapeutic profile may result in black-box label or discontinuation. Investors should take note of the risk of volatility inherent in the price of Biotech stocks.

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As at 31 March 2019.

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