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# Galapagos NV GLPG.OQ GLPG US

**EQUITY:** AMERICAS BIOTECHNOLOGY

## FDA Meeting Sees Early NDA, More July 30

# Quick Note

GLPG's partner GILD announced yesterday evening an update from their pre-NDA meeting with the FDA on filgotinib NDA submission plans. GILD discussed Ph3 FINCH results and MANTA trials/data requirements with the FDA and reached an agreement for a 2019 NDA submission. This is consistent with our view that a YE19 filing was likely, despite MANTA study enrollment and data requirement concerns. *Clarity from the FDA represents upside to consensus expectations that saw MANTA trial completion as a requirement for NDA filing*. No update was provided on whether the NDA submission will be rolling, or if NDA acceptance (i.e., filing) or approval is contingent upon MANTA completion (est. in 2020). Further, no indication was provided if a PRV would be utilized for filgotinib in RA. We anticipated that this update would be provided on the company's 2Q19 earnings call. We now expect GILD to provide more color (including potential PRV use, and rolling vs. non-rolling submission for filgo) on the call scheduled for July 30, 4:30pm ET. *Reiterate Buy.*

- **PRV or No PRV – Current Path Could See PDUFA as Early as 1H20.** We note GILD has one remaining PRV that may be used to speed the filgotinib NDA review. It is unclear to us if discussions with regulators included use of the PRV. Our expectation is that GILD will use the PRV, given its increased focus on the program and competitive upadacitinib launch. A filgo PDUFA in 1H20 is the most rapid timeline available to the company. Further, it is unclear if the NDA will be a rolling submission and to what extent MANTA data will be required.
- **MANTA Still Matters: Data Expected 2020, and the FDA Has Recently Addressed JAK Safety Post Approval.** GILD's update from the pre-NDA meeting discussions with the FDA suggest that partial data from MANTA may be sufficient to support a filing; it remains unclear to us if full results (or full enrollment in MANTA or MANTA-RAy) would be required for approval (not likely, in our view). A negative finding from MANTA (though unlikely, in our view) could impact filgo's label. MANTA is not addressing a manifest safety issue observed in humans; instead, it is ruling out a theoretical risk, based on pre-clinical findings of decreased sperm counts in animals at doses >200mg. *Further, we point out more serious safety issues uncovered in post-marketing studies have triggered post-approval changes to prescribing and or labeling for other JAK inhibitors*.
- **MANTA-RAy Enrolled Patients to Be Pooled with MANTA.** Clinicaltrials.gov indicates that MANTA-RAy results may be pooled with the results of MANTA; the total number of participants in both studies combined will be 250. MANTA started in July 2017. We noted, in January, that we expect MANTA recruitment to accelerate, as the study was up to 94 sites from 84 on the last update (Jan.); MANTA-RAy should further accelerate recruitment.
- **Approval on Both Doses?** No update was provided on the doses for which GILD/GLPG will seek approval. We see no reason for approval of only a single dose, given strong safety to date of both high and low doses.

**Instinet, LLC, Equity Research**

2 July 2019

| | |
|---|---|
| **Rating** Remains | **Buy** |
| **Target Price** Remains | USD 140.00 |
| **Closing price** 1 July 2019 | USD 130.44 |

## Research analysts

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## EULAR Presentation Highlights GILD's Potential Path to *Label Differentiation* for Filgotinib

- **Could the FDA's Flexibility Be Due to Filgo's Differentiated Safety from Other JAK Inhibitors?** We noted that GILD/GLPG presented a poster at EULAR that, for the first time, attempted to explain the potential biological basis for lower PE/VTEs observed in the filgotinib development program (note). We anticipate that the companies will leverage this data to negotiate the cleanest label possible.
- **JAK1 Selectivity and Filgo's Advantage Borne Out in CETP Inhibition?** GILD, GLPG's partner, presented a poster, "*In Vitro Mechanistic Studies Demonstrate Filgotinib Activity That Has Potential Implications for Differentiation Among JAK Inhibitors".* The work suggests filgotinib inhibits CETP; CETP is increased in VTE subjects and increases LDL:HDL ratios. This was an effect observed for filgo but not for other JAK inhibitors tested (upa, bari, tofa). Other data demonstrated that filgo had no MOA-dependent effect detected for changes in hemoglobin, and IL-15-stimulated NK-cell proliferation is less inhibited with filgo vs. other JAK inhibitors.
- **Lower Herpes Zoster Caught MDs Eye at EULAR.** Herpes zoster was not increased in the filgo groups, compared to the control groups, and this may differentiate filgotinib from other JAK inhibitors (based on cross-trial comparisons). There was some slight infection risk elevation in filgo (particularly at 200mg) vs. placebo, but it is lower than adalimumab.

# Appendix A-1

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| Issuer | Ticker | Price | Price date | Stock rating | Sector rating | Disclosures |
|---|---|---|---|---|---|---|
| Galapagos NV | GLPG US | USD 130.44 | 01-Jul-2019 | Buy | Not rated | A4,A5,A6,A7 |

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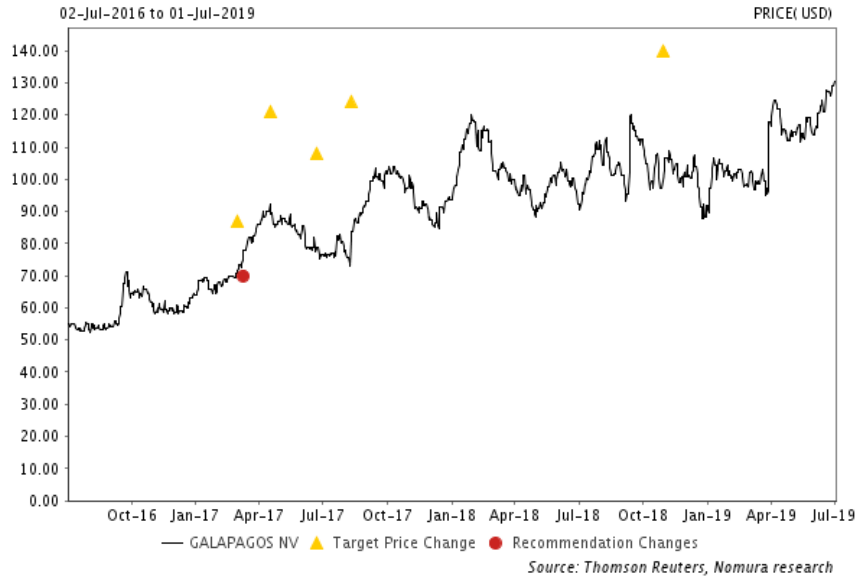
**Galapagos NV (GLPG US)** **USD 130.44 (01-Jul-2019)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)




| Date | Rating | Target price | Closing price |
|---|---|---|---|
| 30-Oct-18 | | 140.00 | 99.55 |
| 10-Aug-17 | | 124.00 | 81.06 |
| 22-Jun-17 | | 108.00 | 78.56 |
| 17-Apr-17 | | 121.00 | 92.40 |
| 01-Mar-17 | Buy | | 71.78 |
| 01-Mar-17 | | 87.00 | 71.78 |

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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