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Galapagos NV GLPG.OQ GLPG US

EQUITY: AMERICAS BIOTECHNOLOGY

EULAR: PsA and Filgos RA Label Advantage?

Quick Note

GLPG and their partner GILD presented updated results from multiple clinical programs for filgotinib at EULAR (June 12-15, Madrid) – though the FINCH 1 & 3 results stole the show with late-breaking presentations. GLPG also presented posters from EQUATOR for filgo in PsA and additional biomarker studies. See **Fig. 2** for presentation titles by category. FINCH 1 (pt with inadequate response to MTX) and FINCH 3 (pts naive to MTX) updated datasets were unsurprising – however, new data supporting filgo's improved VTE profile vs. other JAK inhibitors suggests 1) VTE is not a class effect and 2) that GILD/GLPG may be presenting a case to support a differentiated label with respect to safety. Beyond RA, PsA patient outcomes are encouraging. We continue to see next indications (IBD, and PsA) for filgo as overlooked and upside to GLPG's current valuation. *Reiterate Buy.*

- **FINCH 1 & 3 Updates – No Surprises, Rapid Onset**, **Safety Remains Encouraging.** We previously discussed FINCH 1 & 3 top-line results here. No new safety findings were reported, though one year follow-ups and pooled data (including LTE studies) will be important. Rapid onset of action was noted as impressive, particularly in FINCH 1 vs. adalimumab.
- **EULAR Physician Uncertainty Over Filgo Monotherapy 200mg Superiority to MTX and Numerical Differences That Didn't Reach Significance.** In FINCH 3, monotherapy of filgo at 200mg missed on superiority vs. MTX for ACR20; however, it looks superior on ACR50 and ACR70 (not adjusted for multiplicity). Radiographic response of filgo monotherapy vs. MTX was, however, superior. FINCH 1 DAS28-CRP analysis vs. adalimumab may have impacted the outcome vs. adalimumab (as IL6 could have been impacted by JAK inhibition) and could have been more positive on ACR50 according to our checks. Recall, the MTX arm performed better, which is potentially indicative of trial design differences (potentially due to geographies) and perhaps expected, given this is the 4th JAK inhibitor. Additionally, more enthusiasm for 200mg based on improved/more consistent activity across studies potentially portends a high-dose only label.
- **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 other JAK inhibitors tested (upa, bari, tofa). Other data demonstrated that filgo had no MOA 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 MD's Eye.** 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.

Instinet, LLC, Equity Research

17 June 2019

Rating Remains	**Buy**
Target Price Remains	USD 140.00
Closing price 14 June 2019	USD 121.18

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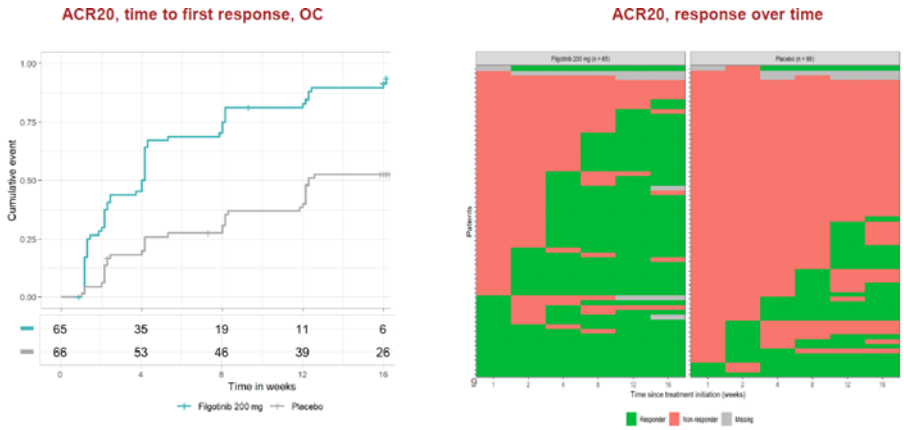
- **Manta Still Matters** – We continually receive investor questions and push back (from the more bearish) on Manta and Manta timelines. GILD still has one PRV remaining (and some will become available shortly). We anticipate they will use this for the filgo NDA. We see the potential for upside with filgotinib filing by mid-2019, which could set up for a near concurrent launch with upa. However, a filgo filing by YE19 is more likely, in our view, if MANTA/MANTA-RAy results become a bottleneck.

Filgotinib for PsA

- **Patient Level Data from EQUATOR Continues to Support Efficacy in PsA.** Recall, EQUATOR Ph2 results were previously published in the Lancet in Dec. 2018 (here). The study hit the primary endpoint, ACR20. This presentation further evaluated the time to first response on a patient level, and the duration of response. Encouragingly, patients had a rapid response that persisted; shown below is the time to first response and response over time of the primary endpoint, ACR20. Additionally, patients on placebo had more occurrences of lost response (similar trends were observed for other efficacy endpoints).

Fig. 1: ACR20 Time to First Response and Response Over Time



Source: Company data

- **Filgo Decreases Inflammatory Biomarkers in PsA, Including Systemic Inflammation Markets, Proinflammatory Mediators, and Matrix-Remodeling/Cell Adhesion Markers.** A poster measuring inflammatory biomarkers in 60 filgo-treated patients and 61 placebo-treated patients noted rapid (in first week) decreases in systemic inflammation markers (CRP and SAA) and proinflammatory mediators (IL-12/23, MIP3beta). Changes in matrix remodeling markers were also rapid, but some (such as MMP1) took more time to reach maximal effect.
- **EQUATOR Ph2 Data on PsAID9 and PROs**. EQUATOR (NCT03101670) tested filgo 200mg against placebo in psoriatic arthritis (PsA), and used ACR20 in PsA as the primary endpoint. Secondary endpoints include the psoriatic arthritis impact of disease (PsAID9) to assess HRQoL and other patient-reported outcomes (PROs)**.** Posters on PsAID9 showed that patient improvements in this endpoint were consistent with the primary clinical outcomes, and because it only uses nine questions, is much simpler than measures such as SF-36.

The Forgotten Pipeline Beyond Filgotinib

- **ROCCELLA Ph2 Enrollment Complete, GLPG1972/S201086 in OA; Data Is Expected by YE20**. Servier and GLPG are testing GLPG1972/S201086, an ADAMTS-5 inhibitor, in >850 patients with knee osteoarthritis (OA) (NCT03595618). A Ph3 is planned pending positive data, but a faster path to approval could also be pursued (GLPG1972 has fast-track designation). GLPG1972 remains upside to our target price.

GLPG's EULAR Posters List

Fig. 2: Presentations at EULAR 2019 by Category

GLPG Presentations at EULAR 2019: Overview of Titles
Filgo Safety
In vitro mechanistic studies demonstrate filgotinib activity that has potential implications for differentiation among JAK inhibitors
Pharmacokinetics and Short-term Safety of Filgotinib, a Selective Janus Kinase 1 Inhibitor, in Subjects With Moderate Hepatic Impairment: a Phase 1, Open-Label, Single-Arm Study
Filgo in RA: General
Selective Inhibition of Janus Kinase 1 (JAK1) by Filgotinib Modulates the Disease-Associated Whole Blood Transcriptional Profile of Patients With Active RA
Filgotinib, a Selective Janus Kinase 1 (JAK1) Inhibitor, Modulates Disease-Associated Cytokines in Patients
Safety and Efficacy of Filgotinib in Patients Aged 65 Years and Older: Results From a Phase 3 Study in Patients With Active Rheumatoid Arthritis and Prior Inadequate Response or Intolerance to Biological DMARDs
Safety and Efficacy of Filgotinib in Active Rheumatoid Arthritis By Prior Biologic DMARD Exposure in Patients With Prior Inadequate Response or Intolerance to Biologic DMARDs (bDMARD-IR)
Filgotinib in Patients with Rheumatoid Arthritis and Prior Inadequate Response or Intolerance to Biologic DMARDs (bDMARD-IR) by Geographic Region and Race
Filgo FINCH Data
Efficacy and Safety of Filgotinib for Patients With Rheumatoid Arthritis Naïve to Methotrexate Therapy: FINCH 3 Primary Outcome Results
Efficacy and Safety of Filgotinib for Patients With Rheumatoid Arthritis With Inadequate Response to Methotrexate: FINCH 1 Primary Outcome Results
Filgo in PsA
Efficacy of Filgotinib vs Placebo in Active Psoriatic Arthritis: Patient- Level Data From EQUATOR, a Randomized, Phase 2 Study
PsAID9 in Patients with Active Psoriatic Arthritis Treated with Filgotinib vs Placebo: Results from EQUATOR, a Randomized, Phase 2 Study
Effect of Filgotinib on Patient-reported Outcomes in Active Psoriatic Arthritis: Results From EQUATOR, a Randomized, Phase 2 Study
Filgotinib Treatment Provides Rapid and Sustained Reduction of Inflammatory Biomarkers in Patients With Moderate to Severe Active PsA
Early Stage Compounds and Biology Insights
GS-9876, a Novel, Highly Selective, Syk Inhibitor in Patients With Active Rheumatoid Arthritis: Safety, Tolerability and Efficacy Results of a Phase 2 Study
IRAK4 Inhibition Suppresses TLR7, TLR9 and SLE Serum-Induced IFNα Production in Primary Human Plasmacytoid Dendritic Cells
TPL2 Inhibition Suppresses MEK-ERK Inflammatory Signaling and Proinflammatory Cytokine Production in Primary Human Monocytes
Targeting activated ASK1 in synovial fibroblasts in combination with JAK1 inhibition enhances efficacy in rat

Source: Company data, Instinet research

Appendix A-1

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Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Galapagos NV	GLPG US	USD 121.18	14-Jun-2019	Buy	Not rated	A4,A5,A6,A7

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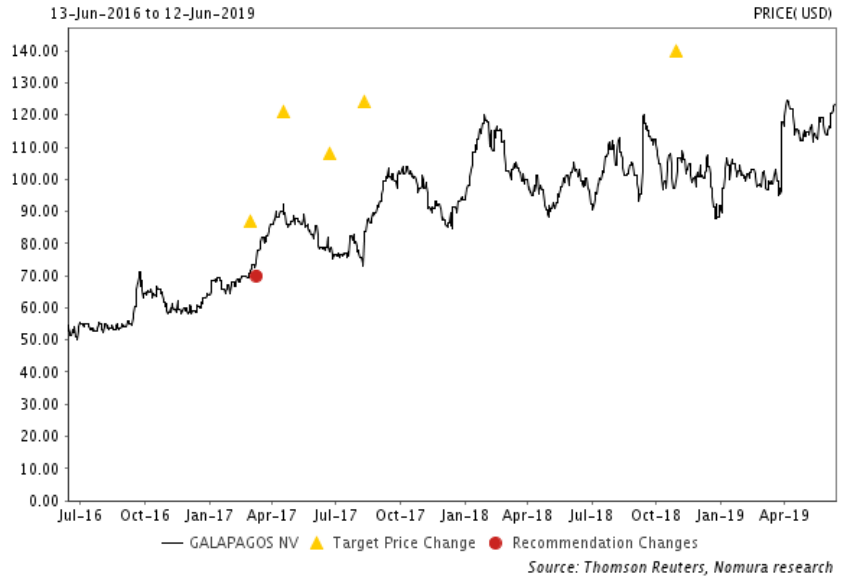
Galapagos NV (GLPG US) **USD 121.18 (14-Jun-2019)** Buy (Sector rating: Not rated)

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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