

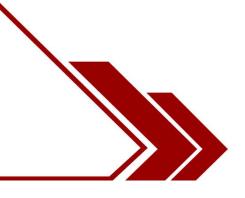
Galapagos NV GLPG.OQ GLPG US

EQUITY: AMERICAS BIOTECHNOLOGY

EULAR Abs: Clean Filgo P2b 108-Wk LTE Data Quick Note

Galapagos and partner Gilead are slated to present a poster with data from their long-term extension P2b study (DARWIN 3) with filgotinib (oral JAK1 inhibitor) in moderate-to-severely active rheumatoid arthritis on June 16, 2018 during a poster session at EULAR. The abstract (#SAT0200; Long Term Safety of Filgotinib in the Treatment of Rheumatoid Arthritis: Week 108 Data from a Phase 2B Open-Label Extension Study) highlighted an impressive long-term safety profile further solidifying filgotinib as the cleanest JAK1 inhibitor (see Fig. 1). Efficacy was also robust and durable with 68% achieving ACR50 and 72% achieving Low Disease Activity (per DAS28-CRP<3.2) at week 108 in 491 patients. This follows the disappointing baricitinib RA ADCOM, where concerns around a dose-dependent increase in VTE (DVT and PE) events shut down any likelihood of a 4mg approval (we don't expect a 2mg approval either, see note). A second baricitinib CRL is a positive for GLPG, in our view, and will focus attention on upadacitinib's nearly comparable VTE rate. We find the EULAR abstract top-line findings from DARWIN 3 LTE safety study to be encouraging and reaffirm our thesis that filgotinib is the best-in-class JAK1 inhibitor.

- Comparable Efficacy and Superior Safety Profile Puts Filgotinib as Best-In-Class, Despite Being Behind. Compared to the updated upadacitinib P2b LTE trial (BALANCE-EXTEND) which had a VTE rate of 0.7 per 100 PYE at 72 weeks, filgotinib's P2b LTE trial (DARWIN 3) impressed with a VTE rate of 0.1 per 100 PYE at 108 weeks. The event occurred in only one patient who experienced a DVT that led to PE. Consider that the ACR and LDA endpoints have been comparable thus far (see note). We believe filgotinib offers a superior profile that de-risks the approval path relative to upadacitinib and in light of baricitinib's unfavorable ADCOM (see note). We note the pooled VTE rates for all baricitinib treated pts from P3 controlled and LTE studies were 0.5 per 100 patient years. Despite being a year behind, we believe filgotinib's undisputed safety profile and robust efficacy will help consolidate front-line position in biologic RA therapy after MTX while ABBV's upadacitinib may face scrutiny (or label-risks) if compiled data indicates dose-dependent increase in VTE.
- FINCH 1 and FINCH 3 Enrolled Ahead of Schedule. On their 1Q18 earnings call, GILD announced that FINCH 1 and 3 are fully enrolled, ahead of schedule, and we look forward to the readout of the P3 study (FINCH 2) in 2H18E with filgotinib in biologic-IR RA pts for further read-through in a placebo-controlled setting and potential efficacy in this later treatment line.
- Making Right Hires Ahead of Commercialization Efforts. Michele Manto joined GLPG as SVP of Commercial Operations last September from ABBV, leaving an outstanding 15-yr tenure and a legendary Humira franchise as the Global General Manager of Rheumatology. We believe Mr. Manto's impressive work with Humira and extensive knowledge of the immunology market will be a tremendous asset to filgotinib's adoption in



Instinet, LLC, Equity Research

17 May 2018

Rating Remains	Buy			
Target Price Remains	USD 124.00			
Closing price 17 May 2018	USD 96.68			

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the EU where GLPG has a 50/50 profit split on the Benelux and EU5 regions and where there is a preference for oral small molecules over injectable.

• Atopic Dermatitis Trial De-prioritized but Not Forgotten. ABBV and PFE have placed their bets on the growing AD market, moving their highly selective JAK1 inhibitors to late-stage trials, GILD has chosen to deprioritize the AD indication with filgotinib, likely due to the high bar set by Dupixent and the bourgeoning size of filgotinib programs. However, we see even greater potential in AD with MOR106, an anti-IL-17C mAb, which in P1 MAD study demonstrated rapid and robust efficacy of 83% of patients reaching EASI50 by Week 4 as well as very clean safety profile with no SAEs or infusion-related reactions. All adverse drug reactions were mild-moderate and transient in nature. We believe the IL-17C cytokine's role in skin inflammation makes it an attractive target for AD. Despite Dupixent's high bar, we look for robust 12 wk EASI scores, safety signals, as well as Q4W (vs. Q2W Dupixent) for market potential as MOR106 moves into the recently initiated larger 180-pt P2 trial (IGUANA).

Fig. 1: P2b Long-Term Extension Study (Filgo	tinib vs. Upadacitinib)					
P2b LTE Results in RA	Filgotinib (LTE P2b)	Upadacitinib (LTE P2b)				
	Efficacy (n/N)					
Data Cutoff (wks)	108	72				
ACR20	87%	87%				
ACR50	68%	65%				
ACR70	48%	44%				
DAS28-CRP LDA (<3.2)	72%	72%				
	Safety (per 100 PYE)					
Patient numbers (n)	739	493				
Patient years of exposure (PYE)	1931	725.1				
AE (per 100 PYE)	146.2	170.5				
Serious Aes (per 100 PYE)	5.7	9.4				
Serious Infections	1.3	2.3				
Malignancy excl. NMSC	0.6	0.8				
VTE (DVT/PE)	0.1	0.7				
Hemoglobin 🗸	0.5	* 2.6	^			
Lymphocytes 🗸	1.2	* 2.3	~			
Neutrophils 🗸	0.3	* 1.4	**			

Note: NMSC - Non-melanoma Skin cancer; * ≥ Grade 3; ^ Anemia; ~ Lymphopenia; ** Neutropenia

Source: Instinet research

Other Relevant EULAR 2018 Abstracts

Upadacitinib (ABBV)

Oral: OP0035 UPADACITINIB AS MONOTHERAPY: A PHASE 3 RANDOMIZED CONTROLLED DOUBLE-BLIND STUDY IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO METHOTREXATE **13.06.2018**

Oral: OP0036 A PHASE 3 RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF UPADACITINIB (ABT-494), A SELECTIVE JAK-1 INHIBITOR, IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WITH INADEQUATE RESPONSE TO CONVENTIONAL SYNTHETIC DMARDS **13.06.2018**

Poster Tour: SAT0219 UPADACITINIB IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGICAL DMARDS: A PHASE 3 RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF A SELECTIVE JAK1 INHIBITOR **16.06.2018**

Poster: SAT0236 LONG-TERM SAFETY AND EFFICACY OF UPADACITINIB (ABT-494), AN ORAL JAK-1 INHIBITOR IN PATIENTS WITH RHEUMATOID ARTHRITIS IN AN OPEN LABEL EXTENSION STUDY **16.06.2018**

Poster: SAT0244 IMPACT OF 12 WEEKS OF UPADACITINIB TREATMENT ON INDIVIDUAL AND COMPOSITE DISEASE MEASURES IN PATIENTS WITH RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO CONVENTIONAL SYNTHETIC OR BIOLOGIC DMARDS **16.06.2018**

Poster: SAT0254 UPADACITINIB IMPROVES PATIENT-REPORTED OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO CONVENTIONAL SYNTHETIC DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS: RESULTS FROM SELECT-NEXT **16.06.2018**

Poster: SAT0255 PATIENT REPORTED OUTCOMES OF UPADACITINIB: RESULTS FROM BIOLOGIC INADEQUATE RESPONDERS (SELECT BEYOND PHASE III TRIAL) 16.06.2018

Poster: SAT0257 A PHASE 2B/3 RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF UPADACITINIB, A SELECTIVE JAK1 INHIBITOR, IN JAPANESE PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS AND INADEQUATE RESPONSE TO CONVENTIONAL SYNTHETIC DMARDS **16.06.2018**

Filgotinib (GLPG/GILD)

Poster: SAT0200 LONG TERM SAFETY OF FILGOTINIB IN THE TREATMENT OF RHEUMATOID ARTHRITIS: WEEK 108 DATA FROM A PHASE 2B OPEN-LABEL EXTENSION STUDY **16.06.2018**

Poster: SAT0231 EFFECTS OF THE JAK1-SELECTIVE INHIBITOR FILGOTINIB ON GENE EXPRESSION PROFILE IN BLOOD OF PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS **16.06.2018**

Baricitinib (INCY, LLY)

Poster Tour: SAT0218 EFFICACY AND SAFETY OF BARICITINIB IN MTX-IR PATIENTS WITH RHEUMATOID ARTHRITIS: 52 WEEK RESULTS FROM A PHASE 3 STUDY (RA-BALANCE) **16.06.2018**

Poster: SAT0237 EFFICACY OF BARICITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO FAILED 2 OR MORE DMARDS 16.06.2018

Appendix A-1

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Materially mentioned issuers

Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Galapagos NV	GLPG US	USD 96.68	17-May-2018	Buy	Not rated	A6

A6 The Nomura Group expects to receive or intends to seek compensation for investment banking services from the subject company in the next three months.

ng and target price chart (three year history) 15-May-2015 to 14-May-2018 .00 .00 .00 .00 .00		10-Aug-17 22-Jun-17 17-Apr-17	Rating	Target price 124.00	Closing price 81.06
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— GALAPAGOS NV 🔺 Target Price Change 🕚 Recommend	lation Changes <i>homson Reuters, Nomura researd</i>				

For explanation of ratings refer to the stock rating keys located after $\mbox{chart}(s)$

Valuation Methodology For Galapagos NV (GLPG), we use a top-line revenue multiple valuation, a method widely used for early-stage biotech companies. Our target price of \$124 represents a 6x multiple for EU profit share on filgotinib across inflammatory indications and a 16x multiple for U.S. royalties on filgotinib. In filgotinib for RA, we apply a 15% discount rate, reflecting a lower development risk, as the target, JAK, is already validated by an approved drug in RA. In filgotinib in UC and Crohn's, we apply a 20% discount rate, reflecting a slightly higher risk for these indications, as no JAK inhibitor is approved. For the Cystic Fibrosis program, we use an 18x multiple, reflecting a higher value for the higher-margin orphan program and a 25% discount that reflects a higher development risk. For the IPF program, we use an 8x multiple, reflecting a higher value for the higher development risk for this stock is the Nasdaq Biotechnology Index.

Risks that may impede the achievement of the target price Regulatory risk: The FDA may require Galapagos to present data on the efficacy of the individual triple-combo drugs in the target patient population, which would require the company to conduct a large Phase 2 study. Enrollment of patients in these studies might be challenging, due to the low expectation of efficacy from a single compound. 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 viability. Competitive risk: Baricitinib, a JAK 1/2 inhibitor, was expected to be approved by January 19, 2017. In clinical studies, the drug presented compelling efficacy superior to adalimumab. If baricitinib is found to be safe and approved without a black-box warning, it could take the lion's share of the market. Celgene's mongersen, an SMAD7 anti-sense RNA, showed compelling safety and efficacy profile in a Phase 2 study in

CD patients. The compound is in a Phase 3 study and is set to report top-line data by 2H18. If approved, mongersen would have first-mover advantage as the only orally available DMT for Crohn's. 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.

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