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Galapagos

Filgotinib stays on the FDA's naughty list – thoughts on last night's announcement

Stock Rating/Industry View: Equal Weight/Positive
Price Target: EUR 125.00
Price (15-Dec-2020): EUR 97.06
Potential Upside/Downside: 29%
Tickers: GLPG NA / GLPG.AS

Not a surprising development; key for us what's NPV impact of GLPG assuming full commercialization in Europe; ISABELA becomes increasingly more binary

Last night, GLPG and filgotinib development partner GILD (covered by Carter Gould; see: *GILD: Filgotinib Restructuring Unsurprising, But Necessary First Step (15/12/20)*) announced that based on feedback from the Type A meeting with the FDA regarding filgotinib's 200mg dose in rheumatoid arthritis, GILD will no longer be pursuing FDA approval in this indication. Furthermore, without a viable path forward in the US, studies in psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-infectious uveitis will be stopped over the coming months. The amended agreement between both companies will now see GLPG take sole development and commercial responsibility for filgotinib in Europe, which includes the already approved indication of RA in addition to any future indications (including UC or CD, which likely are the only indications that would have a path forward).

Given the commentary made by GILD on that company's 3Q call, we can't exactly say this is a surprising development (see: *Galapagos: GILD indicates we could know more on filgo's future by year end (29/10/20)*) and the wording around the path forward for 200mg in the US was the bulk of the rationale as to why we downgraded GLPG following the receipt of the CRL back in August (see: *Galapagos: Filgotinib CRL - downgrade to EW (19/08/20)*).

GILD remains partnered with GLPG for filgotinib in the US for IBD indications, however the path forward here remains contingent on a successful outcome of the MANTA/MANTA-RAy safety studies. GLPG's PR indicated that the week 26 safety data from these will be available by mid-2021 and that the parties expect to submit that data to regulators shortly thereafter. However, last night's release noted that the FDA has requested up to week 52 follow-up data for patients who show a >50% decrease in semen parameters by week 26 and do not recover. We spoke to the company briefly last night who indicated to us that this essentially means that in a best case scenario, UC filing occurs shortly after mid-year 2021 and in a worse case, if full 52 week data is needed, that is likely a mid-2022 event. We hope to learn more on this on today's call.

Given all this, the most pertinent question remains, what does this mean for GLPG shares? Our current NPV for GLPG is €127.29. Taking US RA sales out of this completely reduces that by -3.5%. The analysis of how the revised commercial arrangement in the EU will take some more time to work through in our model. That being said, we believe that expectations will likely be taken down by investors for UC in the US, particularly in light of the recent positive data from Abbvie's Rinvoq (see: *Galapagos / Sanofi: UPDATE: EU implications of a good week for Rinvoq (10/12/20)*) in addition to this MANTA update that could push out timing (at a minimum). **As such, we would expect likely a more negative reaction in GLPG shares than just the removal or US RA sales would suggest and believe that the futility analysis if the USABELA trails of ziritaxestat in IPF (expected in 1H21) is becoming an increasingly binary event.**

GLPG will hold a conference call today at 8am ET / 1pm UK / 2pm CET (+44 2071 928 338, conference code 7689939).

We value filgotinib's contribution to GLPG at an NPV of €41.2/sh in our €127.3/sh GLPG group NPV, based on global peak risked revenues of ~€1.6bn. Our filgotinib global risked revenue estimates are ahead of Bloomberg consensus in the short term (+38% in 2021, +7% in 2022) before descending 25% below consensus in 2023. Bloomberg consensus for global filgotinib sales is calculated as EUR-adj filgotinib estimates from GILD added to GLPG estimates that are grossed up by the Barclays-estimated EU ex-Benelux royalty rate.

Further details from today's announcement

Summary of amended agreement

- **This evening, GLPG and filgotinib development partner GILD (covered by Carter Gould) announced they are amending their filgotinib collaboration agreement, following the Type A FDA meeting.**
- Based on feedback from the Type A meeting, GILD will not be pursuing FDA approval of filgotinib in rheumatoid arthritis.
- GILD concluded that the 200mg dose is required to be competitive in the US rheumatoid arthritis market, and that the chance of approval for this dose is unlikely without substantial additional studies.
- Both companies note they continue to believe in the clinical profile of the 200mg dose.
- Under the new arrangement, GLPG will assume sole responsibility for RA in Europe and will receive payments from GILD regarding the changes to commercialisation and development responsibilities. GILD will receive royalties on EU filgotinib sales.

- This phased transition of responsibilities will see the majority of EU filgotinib activities assumed by GLPG by the end of 2021.

Filgotinib development

- GLPG will assume responsibility for the ongoing RA filgotinib studies.
- The recently paused studies in psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-infectious uveitis will be stopped over the coming months. Without a viable path forward in the US, both companies believe it is no longer feasible to maintain the global development program in these indications.
- MANTA and MANTA-RAy 26-week data on primary and secondary endpoints will be available by mid-2021. The data is anticipated to be submitted to regulatory authorities soon after.
- For the FDA to complete its review in RA and/or other indications, the agency has requested 52-week follow up data for patients who show > 50% decrease in semen parameters by 26 weeks and do not recover in MANTA and MANTA-RAy.
- GLPG and GILD will continue to investigate filgotinib in IBD.
- GILD will retain responsibility for the Crohn's disease studies, while GLPG will assume responsibility for ongoing UC trials.
- Japan submission for ulcerative colitis is anticipated in 1H21. The EU submission is currently under review.
- Further information on the IBD US filing is anticipated after consultation with the FDA, which will include discussing MANTA and MANTA-RAy results.

Financial terms

- GLPG will assume all development, manufacturing, commercialisation and certain other rights for filgotinib in Europe. The transition of responsibilities will include transfer of filgotinib's marketing authorisation.
- Most activities are anticipated to be transferred from GILD to GLPG by 31st December 2021 with full transition anticipated to complete by 31st December 2022.
- All commercial economics for filgotinib in Europe will transfer to GLPG from 1st January 2022 subject to the payment of tiered royalties of 8% to 15% of net EU sales to GILD starting in 2024.
- GILD has agreed to pay GLPG €160m (€110m in 2021 and €50m in 2022), subject to adjustments for any higher-than-budgeted development costs.
- GLPG will no longer be eligible to receive future milestone payments regarding filgotinib in Europe (GILD expect to recognise the full amount of these payments in its R&D expenses in 4Q20).
- From 1st January 2021, GLPG will beat the development costs for certain studies in lieu of the prior agreement for equal cost split. These studies include DARWIN3, FINCH4, FILOSOPHY and P4 studies and registries in RA, MANTA and MANTA-Ray, PENGUIN1,2 and EQUATOR2 (PsA), SEALION1 and 2 (AS), and HUMBOLDT (uveitis).
- GLPG will also be responsible for other clinical and non-clinical expenses supporting these studies, investigator-sponsored trials in non-IBD conditions and non-clinical costs on all current trials.
- The existing 50:50 development cost sharing agreement will continue for SELECTION and its LTE (UC), DIVERSITY and its LTE, and DIVERGENCE 1, 2 and LTE, P4 studies and registries in Crohn's disease, paediatric studies and LTEs in RA, UC and Crohn's, and investigator-sponsored IBD trials.

Recent Barclays Research publications on GLPG

- *Galapagos: No change to collaboration agreement expected in the event of potential GILD merger (07/06/20)*
- *Galapagos: 2Q20 first take: no changes to 2020 goals ahead of the all-important PDUFA (06/08/20)*
- *Galapagos: It's been a cruel summer... (10/08/20)*
- *Galapagos: Filgotinib CRL - downgrade to EW (19/08/20)*
- *Galapagos: Management call recap: a ways to go for filgo (24/08/20)*
- *Galapagos: Ziritaxestat hits in NOVESA phase 2 in SSc (11/09/20)*

- *Galapagos: ROCCELLA fails - quick thoughts (15/10/20)*
- *Galapagos: Toledo to take the salt out of the filgo wound? (27/10/20)*
- *Galapagos: GILD indicates we could know more on filgo's future by year end (29/10/20)*
- *Galapagos: 3Q20 first take: focus will be on filgo commentary on call (05/11/20)*
- *Galapagos: '1205 shows FVC benefit in PINTA; moving on to phase 2b study + thoughts into Type A meeting (01/12/20)*
- *Galapagos / Sanofi: UPDATE: EU implications of a good week for Rinvoq (10/12/20)*

Barclays Research US publications on GILD relevant for filgotinib

- *GILD: Thoughts On Filgo SELECTION Data (20/05/20)*
- *GILD: Takeaways from Today's IBD KOL Call; Implications for Filgotinib (21/05/20)*
- *Gilead Sciences, Inc.: No-Go for Filgo (18/08/20)*
- *Gilead Sciences, Inc.: 3Q20 - Challenging Headwinds to Growth Remain; Lowering PT to $62 (29/10/20)*

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