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**Europe Equity Research** 

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# Neutral

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# Galapagos (GLPG NA)

Key Takeaways from our 2020 CEO Conference Call

Last Monday we hosted a conference call with Galapagos CEO Onno van de Stolpe in the context of the 2020 JP Morgan European Healthcare CEO Conference Call Series (transcript available on request). The call centered on (1.) The ex-US commercial launch of Jyseleca (filgotinib) in RA (Rheumatoid Arthritis) following recent approvals in Europe and Japan, (2.) The possible outcomes in the US following the filgotinib CRL in RA; (3.) Thoughts on filgotinib in UC (Ulcerative Colitis) following the mixed Phase III data and latest timelines for remaining indications; (4.) Pipeline projects, with a focus on ziritaxestat (GLPG'1690) in SSc (Systemic Sclerosis) and IPF (Idiopathic Pulmonary Fibrosis), GLPG'1972 in OA (Osteoarthritis) and the novel TOLEDO programme.

**On the positive side**, Mr. Van de Stolpe stated his view that, irrespective of the outcome of the CRL in RA, GILD remain committed to the development of filgotinib beyond RA.

On the more cautious side, Mr. Van de Stolpe acknowledged that in the event that only the 100mg filgotinib dose receives FDA approval for RA, GILD could choose not to launch in the US for this indication and, under this scenario, GLPG would not take on US commercialisation for this indication themselves.

**Near-term**, we see performance for the remainder of the year driven by the TOLEDO pipeline event on October 27th, as well as Phase II (PINTA) data for GLPG'1205 IPF and Phase II (ROCCELLA) data for GLPG'1972 in OA, both expected by year end, where overall we see balanced risk/reward.

#### Jyseleca (filgotinib)

- GLPG is ready to launch in RA and will start selling shortly: Mr. Van de Stolpe highlighted his excitement around the ex-US commercialisation of Jyseleca, with GLPG already rolling out the launch; first in Germany, where Jyseleca will start to be sold in the coming two weeks, followed by the Netherlands by the beginning of November, and other European countries to follow soon. On pricing and reimbursement, GLPG will not compete on price, with Jyseleca to be priced in line with the other JAKs. On the benchmark for the launch, Mr. Van de Stolpe pointed to Rinvoq and Olumiant, both of which are seeing great uptake in the EU driven by i) oral formulation; ii) on par or better efficacy vs. biologics; iii) lack of need to change therapy over time, and he believes Jyseleca has a very competitive profile, with best-in-class safety, which could be the big point of differentiation. While COVID-19 will have an impact, the teams have prepared for both a virtual and physical launch and are optimistic that they will see good uptake.
- US opportunity in RA hinges on 200mg approval: Following the recent CRL received from the FDA in RA (fist take <a href="here">here</a>), the next step will be a Type A meeting between partner GILD and the FDA in November, to further understand the rationale behind the CRL and the necessary steps required for refiling. While 200mg approval would give Jyseleca the unique proposition of being the only JAK with two dosages in the US, partner GILD don't see a commercial benefit of launching with just the 100mg dose in RA. Should only the 100mg dose receive FDA approval and, under this scenario, should GILD decide not to go forward in RA in the US, Mr. Van de Stolpe doesn't see a scenario where GLPG take on full US RA rights themselves. That being said, he doesn't believe GILD will withdraw from filgotinib entirely should the 200mg dose not get FDA approved in the US for RA.
- GLPG believe IBD (UC and Crohn's) could be an equivalent or bigger commercial opportunity than RA: Mr. Van de Stolpe confirmed that filing for UC in Europe and Japan will be done in 4Q'20 and early-21, respectively, with approval in Europe on track for 2H'21, while the US filing is waiting for the MANTA and MANTA-Ray safety trials to read out in 1H'21. Confidence in Crohn's is high given prior Phase II data and, with the prospect of being the first JAK to market in Crohn's, GLPG believe that ultimately the sales opportunity across UC and Crohn's is as big as, or bigger than in RA.
- CRL in RA could have an impact on RA related diseases: Mr. Van de Stolpe highlighted that the Type A FDA meeting is important with respect to the future of development for PsA (Psoriasis arthritis) and AS (Ankylosing

Spondylitis). The Phase III (PENGUIN) PsA (Psoriatic Arthritis) trials have already started recruiting, but the Phase III (SEALION) AS trial start could be reviewed, as a consequence of the Type A meeting / the CRL.

### Ziritaxestat in SSc and IPF

- Larger Phase II trial might be needed before moving into Phase III for SSc: While GLPG are encouraged by the recent Phase II (NOVESA) readout (first take <a href="here">here</a>), some secondary endpoints were not that meaningful due to a high placebo response, so a larger Phase II trial is likely to precede moving to Phase III development. On safety and FVC (Forced Vital Capacity) data, to be presented at an upcoming scientific conference, GLPG have not yet disclosed the nature of the reported serious adverse events and cautioned on reading across to IPF given different patient populations.
- Futility analysis in IPF on track for the of 1H'21: Recruitment of the Phase III (ISABELA) trial has picked up following the COVID-19 slowdown, with the company now close to 1,200 patients recruited, and the futility analysis on track for the end of 1H'21.

# GLPG'1972 in OA

• Data supports effect on cartilage breakdown but improvement on pain is likely a prerequisite for Phase III: Mr. Van de Stolpe confirmed that GLPG will disclose both primary and secondary endpoints (incl. WOMAC score) with the headline data in 4Q'20. Pre-clinical and Phase I data seen to date supports an effect on cartilage breakdown, but the FDA is focused on pain.

# <u>Oth</u>er

- **TOLEDO programme:** GLPG are starting four Phase II trials by YE'20.
- 4Q'20 catalysts: Phase II (ROCCELLA) data for GLPG'1972 and Phase II (PINTA) data for GLPG'1205 IPF will come well within the first part of 4Q'20 and the TOLEDO roundtable on October 27 will address why GLPG believe TOLEDO can be a game changer for inflammatory and fibrotic diseases.
- Cash burn: Cash burn will increase in 2021 as GLPG expand their commercial efforts in UC.
- Capital allocation: Mr. Van de Stolpe highlighted that, with €5.5bn cash on hand, the company can handle a few years of serious cash burn without any problems and will have enough money available for M&A activities. In addition to smaller in-licenses, GLPG are also considering larger acquisitions with Phase II products, with continued focus on inflammation and fibrosis.

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26-Oct-18	OW	86.04	125
15-Jul-19	OW	128.15	165
15-Aug-19	OW	152.05	170
06-Jan-20	N	188.40	185
24-Sep-20	N	118.70	130

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends. Initiated coverage Sep 12, 2018. All share prices are as of market close on the previous business day.

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