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Equity Research

Healthcare | European Pharmaceuticals

27 October 2020

Galapagos

Toledo to take the salt out of the filgo wound?

This afternoon, we joined Galapagos's much-anticipated event revealing the target and mechanism of action for the key pipeline program, heretofore known as Toledo. Management confirmed that the target of the Toledo compounds is indeed Salt-Inducible Kinases (SIKs). In targeting SIK, Toledo compounds have a dual mechanism of action whereby they reduce pro-inflammatory macrophages and cytokines and induce immunoregulatory macrophages and cytokines. The lead Toledo asset, GLPG3970, targets SIK2/3 and recently moved into multiple POC trials. This was followed by SIK3 targeting GLPG4399, which is IND ready, and a next-generation SIK2/3 targeting compound, GLPG4605. The company plans to introduce more SIK targeting compounds in 2021.

Today's program was very heavy on the science behind the program, which at a high level appears to be quite compelling and the management team's enthusiasm around the program is certainly palpable. However, we will need to see proof-of-concept data before adding any contribution from Toledo to our financial model. Thus, the most tangible information we learned from today's event was more detailed information about the clinical trials underway for '3970 and also around timelines for the program. Three PoC trials are ongoing with two more to start immanently; the first top-line data is expected in mid-2021. If these PoC trials are successful, phase 3 testing could begin in 2022.

With top-line data set to be released mid-next year, 2021 will be another busy year for GLPG, with the interim analysis of the ph 3 ziritaxestat ISABELA trials in IPF expected in 1H21. However, we downgraded GLPG to EW following the receipt of the CRL for filgotinib in RA (see: *Galapagos: Filgotinib CRL - downgrade to EW (19/08/20)*) as we believe that more clarity is needed on the approvability of that asset in both RA and UC before we see new money coming into the name.

GLPG.AS: Financial and Valuation Metrics EPS EUR

FY Dec	2018	2019	2020	2021	2022
EPS	-0.56A	2.49A	-4.49E	-5.42E	-1.93E
Previous EPS	-0.56A	2.49A	-4.49E	-5.42E	-1.93E
Consensus EPS	-0.56A	2.49A	-3.77E	-4.13E	-3.47E
P/E	N/A	43.4	N/A	N/A	N/A

Source: Barclays Research.
Consensus numbers are from Bloomberg received on 27-Oct-2020; 12:50 GMT

Stock Rating	EQUAL WEIGHT Unchanged
Industry View	POSITIVE Unchanged
Price Target	EUR 125.00 Unchanged
Price (26-Oct-2020)	EUR 108.00
Potential Upside/Downside	+15.7%
Tickers	GLPG NA / GLPG.AS
Market Cap (EUR mn)	7057
Shares Outstanding (mn)	65.34
Free Float (%)	64.37
52 Wk Avg Daily Volume (mn)	0.6
Dividend Yield (%)	N/A
Return on Equity TTM (%)	4.09
Current BVPS (EUR)	42.50

Source: Bloomberg

Price Performance	Exchange-AEX
52 Week range	EUR 252.90-99.86

Source: IDC; Link to Barclays Live for interactive charting

European Pharmaceuticals

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European Pharmaceuticals **Industry View: POSITIVE**

Galapagos (GLPG.AS)

Stock Rating: EQUAL WEIGHT

Income statement (€mn)	2019A	2020E	2021E	2022E	CAGR
Revenue	896	556	617	926	1.1%
Gross profit	896	556	617	889	-0.2%
EBITDA (adj)	383	-186	-251	-62	N/A
EBIT (adj)	370	-209	-277	-99	N/A
Pre-tax income (adj)	150	-292	-357	-135	N/A
Net income (adj)	150	-293	-357	-128	N/A
EPS (adj) (€)	2.49	-4.49	-5.42	-1.93	N/A
Diluted shares (mn)	60.2	65.2	66.0	66.6	3.4%
DPS (€)	0.00	0.00	0.00	0.00	N/A

Margin and return data					Average
Gross margin (%)	100.0	100.0	100.0	96.1	99.0
EBIT (adj) margin (%)	41.3	-37.5	-44.8	-10.7	-12.9
Pre-tax (adj) margin (%)	16.7	-52.5	-57.9	-14.6	-27.1
Net (adj) margin (%)	16.7	-52.6	-57.9	-13.9	-26.9
ROCE (%)	30.3	-3.8	-5.5	-2.1	4.7
ROE (%)	12.3	-10.2	-14.0	-6.3	-4.5

Cash flow and balance sheet (€mn)					CAGR
Change in working capital	2,817	-382	-108	-169	N/A
Cash flow from operations	3,209	-585	-440	-259	N/A
Capital expenditure	-22	-27	-33	-49	N/A
Free cash flow	3,186	-611	-473	-308	N/A
Tangible fixed assets	66	91	124	173	37.9%
Intangible fixed assets	25	39	39	39	16.3%
Cash and equivalents	5,781	5,174	4,702	4,393	-8.7%
Total assets	6,069	5,598	5,061	4,838	-7.3%
Short and long-term debt	6	27	27	27	64.0%
Other long-term liabilities	7	11	11	11	15.2%
Total liabilities	3,193	3,042	3,021	3,073	-1.3%
Total invested capital	1,020	592	548	582	-17.1%
Net debt/(funds)	-5,775	-5,147	-4,674	-4,366	N/A
Provisions	0	0	0	0	N/A
Minorities	N/A	N/A	N/A	N/A	N/A
Shareholders' equity	2,876	2,556	2,040	1,765	-15.0%

Valuation and leverage metrics					Average
P/E (adj) (x)	43.4	N/A	N/A	N/A	43.4
EV/sales (x)	1.5	3.5	3.9	2.9	3.0
EV/EBITDA (adj) (x)	3.4	-10.4	-9.6	-44.3	-15.2
Equity FCF yield (%)	49.0	-8.7	-6.6	-4.3	7.4
P/FCF (x)	2.0	-11.5	-15.1	-23.3	-12.0
P/BV (x)	2.3	2.8	3.5	4.1	3.1
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Total debt/capital (%)	0.1	0.5	0.6	0.6	0.5
Net debt/equity (%)	-200.8	-201.4	-229.1	-247.3	-219.7

Selected operating metrics					Average
SG&A/sales (%)	11.0	35.2	39.0	29.9	28.8
R&D/sales (%)	47.7	102.7	111.1	85.2	86.7
R&D growth (%)	32.3	33.8	20.0	15.0	25.3
SG&A growth (%)	147.1	99.1	22.9	15.0	71.0

Source: Company data, Bloomberg, Barclays Research
Note: FY End Dec

Price (26-Oct-2020)	**EUR 108.00**
Price Target	**EUR 125.00**

Why Equal Weight? Whilst data from clinical studies would indicate that filgotinib is the most efficacious and cleanest JAK from a safety profile perspective, the CRL from the FDA calls into question whether the 200mg dose is approvable which would significantly blunt the commercial opportunity for filgotinib.

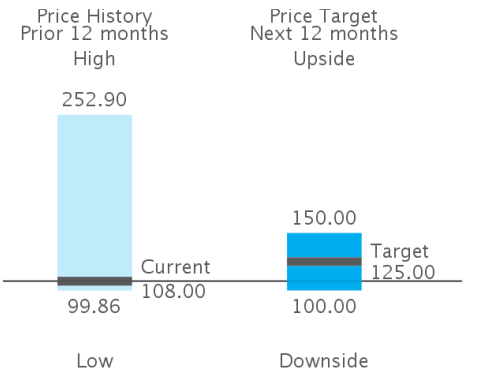
Upside case **EUR 150.00**

Should the MANTA safety study read out positively, it would likely mean filgotinib would be the best-in-class JAK and we would increase our peak share assumptions. Success in the phase 3 trials for IPF asset GLPG 1690 would also result in us raising our NPV.

Downside case **EUR 100.00**

Any safety signals for filgotinib in MANTA or failure of the asset in the IBD ph. 3 trials. Inability of GLPG 1690 to show disease modification in IPF would also lower our peak sales estimates.

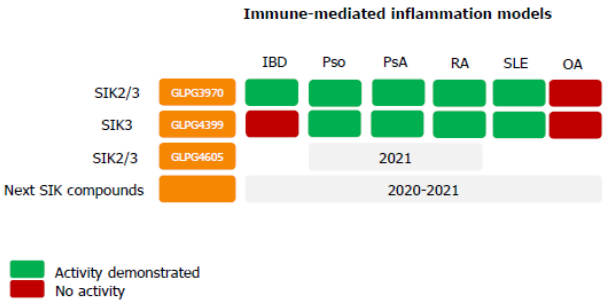
Upside/Downside scenarios



Management's remarks

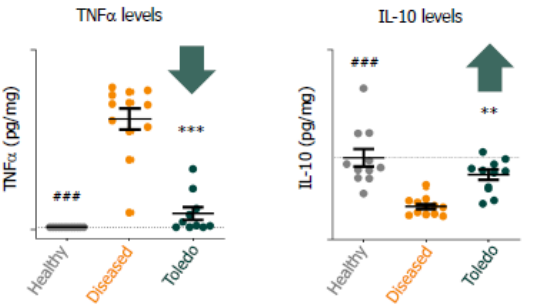
- **Innovation approach**: Every year, the plan is to deliver six new targets, three preclinical candidates and three PoC studies such that one P3 study can be initiated every 2 years.
- **Toledo dual MOA**: Restores immune balance by inhibiting both dendritic cells and macrophages, lowering pro-inflammatory cytokine levels e.g. TNF-alpha, IL-12, and IL-1b while also increasing anti-inflammatory cytokines e.g. IL-19.
- **Broad *in vivo* activity**: Both GLPG3970 (SIK2/3 inhibitor) and GLPG4399 (SIK2 inhibitor) have shown broad *in vivo* activity across a number of immune-mediated inflammation models such as psoriatic arthritis and SLE, while activity for GLPG4605 (SIK2/3 inhibitor) and next SIK compounds should be disclosed in due course

FIGURE 1
Broad in vivo activity



Source: Company presentations

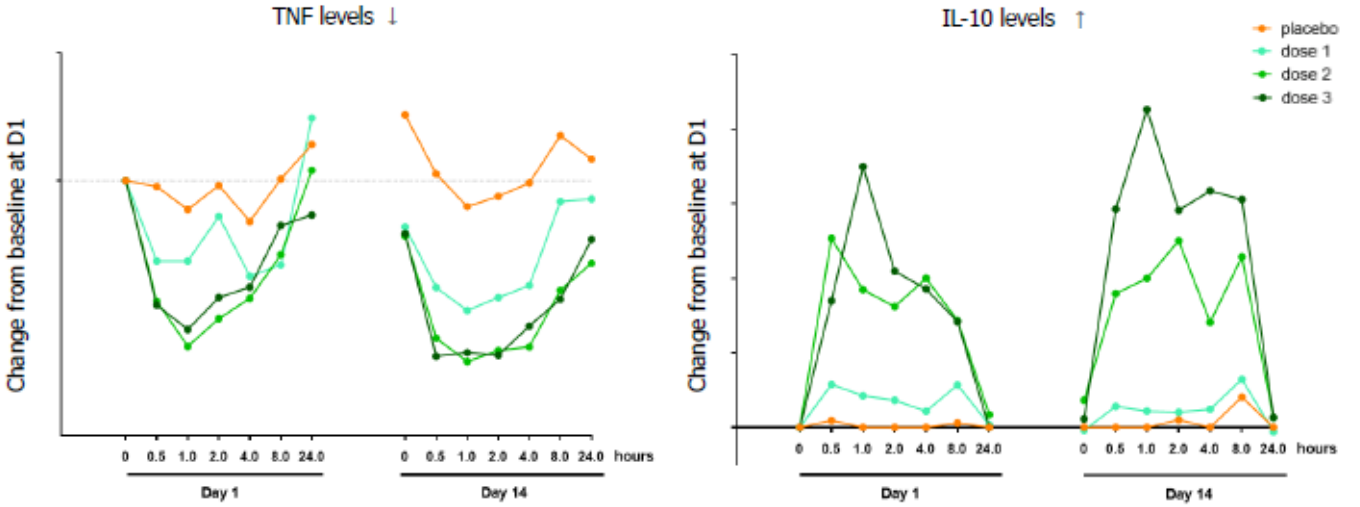
FIGURE 2
Dual MoA of Toledo



Source: Company reports

- **Ex-vivo analysis from P1:** GLPG3970 (3 doses) was evaluated in 59 healthy pts in a P1 study over 14 days. Patients were dosed orally QD. Pharmacokinetics demonstrated fast absorption and dose-proportional exposure with half-life supporting once daily dosing. Dual activity was also confirmed with *ex vivo* analysis in whole blood showing a decline in TNF and an increase in IL-10 levels across all three doses from Day 1 to Day 14. Safety was also shown to be tolerable.

FIGURE 3
Whole blood ex vivo analysis



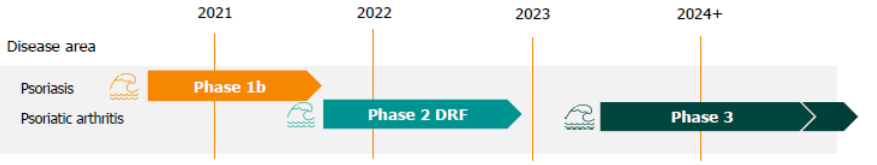
Source: Company presentations

- **Clinical development:** 25% of GLPG R&D staff is currently working on the Toledo programme. In terms of progress, GLPG3970 is the most advanced and is currently in P2 (multiple PoCs), while GLPG4399 is IND ready and GLPG4605 (PCC). Specifically, '3970 is being investigated in psoriasis (6 weeks, active recruitment), ulcerative colitis (PoC study called SEA TURTLE, 6 weeks, active recruitment of 25 patients), RA (PoC study called LADY BUG, 6 weeks, active recruitment of 30 patients), SLE (PoC in preparation), and Primary Sjögren's syndrome (PoC in preparation).

- **Clinical strategy: 1)** Validate the biological pathways of SIK2/3 inhibition by investigating GLPG3970 in PoC studies in psoriasis, UC, RA, SLE, and pSS. **2)** Advance into dose-ranging expansion studies if PoC is successful and expand, e.g. if positive in UC then also expand into CD. **3)** Initiate P3 in auto-immune indications and also investigate Toledo in fibrotic indications, as robust fibrosis activity has also been demonstrated *in vivo* with GLPG3970 in both a lung fibrosis and chronic GvHD skin fibrosis model. As such there is a broad application for the platform. Expecting top-line data as of mid-21.

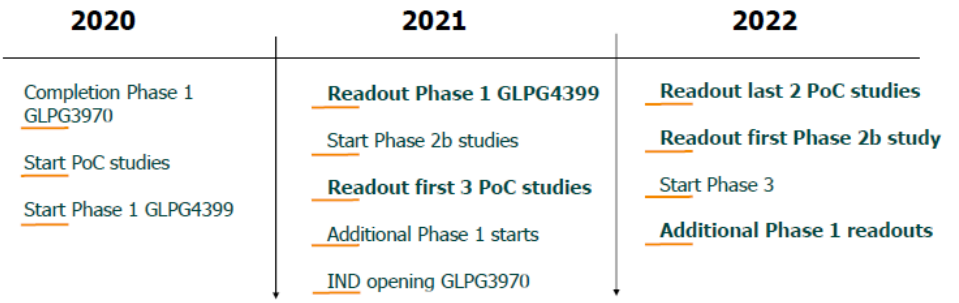
- **Psoriasis validation plan/timelines:** GLPG do not plan to pursue Toledo in psoriasis and are purely investigating patients with this disorder in a P1b study called CALOSOMA (6 weeks, 25 pts) to validate the pathway and determine next steps. The plan is to focus on psoriatic arthritis as there is belief that the probability of success is high for GLPG3970 in this indication. As such, GLPG plan to initiate a P2 dose ranging study in psoriatic arthritis mid-21 after completion of P1b in psoriasis with potential P3 anticipated mid-2023. If progress goes according to plan, then timelines could be shortened by 18-24 months. See timelines below for other plans.

FIGURE 4
GLPG3970 clinical strategy in psoriatic arthritis



Source: Company presentations

FIGURE 5
Timeline for Toledo Programme



Source:: Company presentations

Q&A

- **Differences between '3970 and '4605:** Both compounds have different chemical scaffolds. As such, '4605 concentrates in higher amounts in certain tissues while '3970 concentrates more pervasively.
- **Risk of carcinogenicity from SIK dysregulation**: Any drug that modulates immune pathways carry such a risk, so care needs to be taken. Clinical studies haven't yet begun but there are no signals from preclinical studies that would be cause for concern in terms of cancer risk.
- **Competitiveness of SIK2/3 inhibitors vs. TYK2 and PDE4 in psoriasis**: GLPG are not planning on entering the psoriasis market with SIK2/3 inhibitors. The purpose of the P1b psoriasis study is purely for signal detection and to better understand the biology. There is no intention to commercialise Toledo in psoriasis. Positive data from this study will be used to advance Toledo in psoriatic arthritis.
- **Synergies between '1690 and SIK2/3 in IPF**: Makes sense to combine to gain synergies and completely block progression in diseases like IPF.
- **Confidence that Toledo can gain traction/clinical bar**: Guided by science and based on preclinical data, there is reason to believe this platform could be a paradigm changer. There is also significant room for improvement; currently, steroid free survival rate in the maintenance IBD setting is ~30/40% but they would like to see 90% and even no

patients remaining on steroids longer term. As such, significant unmet need still exists for a number of these auto-immune diseases and GLPG are confident in the science seen so far.

- **R&D spend trajectory**: There has been heavy investment in the programme to date, but it only constitutes a fraction of total GLPG R&D spending and the company is very well capitalised with strong cash balance. They have funds from GILD to invest in innovative new research and this programme fulfils this criteria, so a broad P2 trial is warranted and manageable from a P&L perspective. The key will be whether the data from these trials will support going into multiple P3 studies. By reminder, it is at the P3 stage that GILD has the option to 'opt-in' on a per molecule basis at which point costs will be shared 50/50.

- **'3312 de-prioritisation/lack of selectivity**: '3312 is not as selective as it is a pan-SIK and was simply de-prioritised as the programme progressed very slowly due to a technical issue. At the same time, '3970 was moving a lot faster, so the team decided to switch to the faster progressing programme. Additionally, the impression from '3312 was that the way forward to improve was to make the compound more selective.

- **Toledo dosing**: The fact that the compound plays both ends (dual mechanism) should, in theory, allow for higher dosing on dose response curve, as it won't exhaust system. Additionally, dosing in PoC studies will be in line with the dosing levels used in the P1 study for GLPG3970, but DR studies will investigate a number of doses to see the various impacts on a number of cytokines.

- **Selectivity on indications going forward**: Ambition is that the lead compound, GLPG3970, will show positive data in a number of indications that will subsequently allow the company to focus on multiple indications. GLPG will use the pharmacodynamic fingerprint of each molecule to guide and focus indications.

- **Safety:** No safety issues of concern noted thus far and dual mechanism of action means there appears to be an absence of side effects typically seen with traditional anti-inflammatories.

- **Other MOAs of interest beyond kinase inhibitors**: Open to novel modalities such as interfering with AMP binding domain.

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Primary Stocks (Ticker, Date, Price)

Galapagos (GLPG.AS, 26-Oct-2020, EUR 108.00), Equal Weight/Positive, FC/J

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IMPORTANT DISCLOSURES

Galapagos (GLPG NA / GLPG.AS)

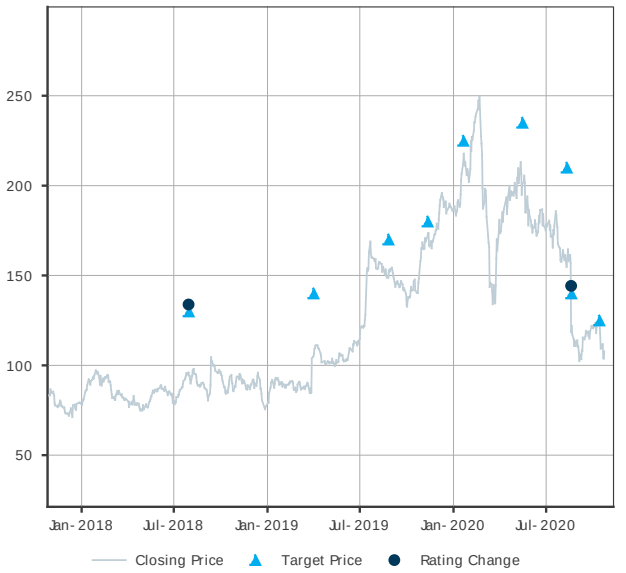
EUR 108.00 (26-Oct-2020)

Stock Rating
EQUAL WEIGHT

Industry View
POSITIVE

Rating and Price Target Chart - EUR (as of 26-Oct-2020)

Currency=EUR



Publication Date	Closing Price	Rating	Adjusted Price Target
13-Oct-2020	124.65		125.00
19-Aug-2020	118.55	Equal Weight	140.00
10-Aug-2020	154.75		210.00
15-May-2020	200.90		235.00
20-Jan-2020	212.20		225.00
11-Nov-2019	171.60		180.00
26-Aug-2019	148.80		170.00
01-Apr-2019	104.95		140.00
30-Jul-2018	96.00	Overweight	130.00

Source: Bloomberg, Barclays Research

Historical stock prices and price targets may have been adjusted for stock splits and dividends.

Source: IDC, Barclays Research

Link to Barclays Live for interactive charting

FC: Barclays Bank PLC and/or an affiliate beneficially owns a short position of more than 0.5% of a class of equity securities of Galapagos, as calculated in accordance with EU regulations.

J: Barclays Bank PLC and/or an affiliate is a liquidity provider and/or trades regularly in the securities by Galapagos and/or in any related derivatives.

Valuation Methodology: Given that we do not expect Galapagos to be profitable until 2023, we employ an NPV-based methodology to derive our price target. Using a 10% WACC and 0% terminal growth rate, we arrive at a price target for GLPG of EUR 125.

Risks which May Impede the Achievement of the Barclays Research Valuation and Price Target: MANTA study showing a safety signal. FDA ruling class effect for safety for JAKs that limits uptake for the class. Failure of filgotinib in ph. 3 IBD trials. Failure of GLPG 1690 to show disease modification in IPF.

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