



19th August 2020

## GALAPAGOS

| Healthcare  
| Biotech

## BUY

Fair Value EUR175 vs. EUR215 (+12%)  
Share price EUR156.70  
EPS 3Y Cagr NM

## Highly surprising move from the FDA as Filgotinib receives CRL

## Kind of worst case scenario for filgotinib in the US

Yesterday evening, Galapagos and its partner Gilead have announced that they have received a complete response letter (CRL) from the US FDA for filgotinib's NDA. FDA is indeed requesting data from the safety studies MANTA and MANTA-RAY studies before completing its review of the NDA while raising concerns regarding the overall benefit/risk profile of the filgotinib 200mg dose. We see this development as all the more surprising considering that the CHMP has just adopted a positive opinion for both two doses of filgotinib. On top of that we clearly understood in the past that full findings from those studies were not necessary for approval. We were expecting that they would have been submitted once completed as a post-approval requirement. Regarding the 200mg, we previously acknowledge that there was a risk that FDA would take a conservative approach and approve only the lower dose. We do believe that FDA concerns on the highest dose are potentially driven by testicular toxicity seen in earlier trials, and that positive results from both MANTA and MANTA-RAY will allow both doses to be approved. This current situation is definitely our worst case scenario for filgotinib in the US.

## MANTA unlikely to show testicular toxicity

Potential testicular toxicity has always been a specific area of controversy for filgotinib. Concerns were first raised during the phase II trials (DARWIN) where the FDA limited the daily dose at 100mg among men at US clinical trial sites on the back of pre-clinical findings suggesting that the 200mg dose affected the production of sperm cells. Thankfully, Galapagos reported that testosterone levels of males in the DARWIN program were stable, allowing the company to include both doses in the pivotal program (FINCH). In addition to that, Galapagos launched trials (MANTA & MANTA RAY) to assess whether filgotinib has an impact on sperm parameters. As reported before, we believe that the design of the MANTA trial set a low bar for the trial to succeed in our view. Based on observations from previous trials and literature on JAKs, we see very limited if no evidence on the impact of JAK on spermatogenesis, especially at levels in humans that would trigger safety concerns. Both studies are fully recruited and results should be presented early next year, allowing the Gilead and Galapagos to file again.

## FV reduced to EUR175 but we are reiterating BUY rating

We are reducing our FV from EUR215 to EUR175 (PoS reduced from 90% to 80% and launch delayed to 2022 in the US) but we are confirming our BUY rating. We are now expecting filing to happen somewhere in H1 2021 on the back of MANTA and MANTA-RAY results, meaning that final decision from the FDA could take place before the end of 2021. We are not anticipating any impact on the European regulatory process at this point. However, it should have an impact on UC filing that would be done now separately and not anymore as supplemental application which could slightly impact timing.

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## Market Data

|                        |                     |
|------------------------|---------------------|
| Bloomberg / Reuters    | GLPG BB/GLPG.BR     |
| Market Cap.            | EUR10,225m          |
| E.V.                   | EUR8,378m           |
| Free Float             | 65.6%               |
| Avg. Daily volume (6m) | 539.6               |
| 12m high / low         | EUR249.5 / EUR132.7 |
| Ytd Perf.              | -16.0%              |

| EURM       | 12/19 | 12/20e | 12/21e | 12/22e |
|------------|-------|--------|--------|--------|
| Sales      | 895.9 | 643.7  | 601.1  | 743.9  |
| % Change   |       | -28.2% | -6.6%  | 23.8%  |
| EBITDA     | NM    | NM     | NM     | NM     |
| % Change   |       | ns     | ns     | ns     |
| EBIT       | 370.3 | -158.5 | -226.4 | -97.1  |
| % Change   |       |        | -42.8% | 57.1%  |
| Net Income | 150.1 | -152.7 | -222.4 | -95.0  |
| % Change   |       |        | -45.7% | 57.3%  |
| ROE        | NM    | NM     | NM     | NM     |

|           | 12/19 | 12/20e | 12/21e | 12/22e |
|-----------|-------|--------|--------|--------|
| EV/Sales  | 9.4x  | 13.9x  | 15.9x  | 13.5x  |
| EV/EBITDA | x     | x      | x      | x      |
| EV/EBIT   | 22.6x | NS     | NS     | NS     |
| EPS       | 2.32  | -2.36  | -3.44  | -1.47  |
| % change  |       |        | -45.7% | 57.3%  |
| P/E       | 67.5x | NM     | NM     | NM     |
| Div Yield | NM    | NM     | NM     | NM     |

Next Catalyst : Q3 2020: 5 November

## Last FV Change:

[2020-7-31, Some reasons to be cautious but current valuation is hard to justify anyway](#)

## Last Reports:

[2020-7-31, Some reasons to be cautious but current valuation is hard to justify anyway](#)

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### Stock rating

|                |   |
|----------------|---|
| <b>BUY</b>     | Positive opinion for a stock where we expect a favourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential upside based on valuation), but also takes into account a number of elements that could include a SWOT analysis, momentum, technical aspects or the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.      |
| <b>NEUTRAL</b> | Opinion recommending not to trade in a stock short-term, neither as a BUYER or a SELLER, due to a specific set of factors. This view is intended to be temporary. It may reflect different situations, but in particular those where a fair value shows no significant potential or where an upcoming binary event constitutes a high-risk that is difficult to quantify. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.                     |
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### Distribution of stock ratings

BUY ratings 54.4%

NEUTRAL ratings 29.5%

SELL ratings 16.1%

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