



2nd July 2019

GALAPAGOS

| Healthcare
| Biotech

BUY

Fair Value EUR140(+23%)
Share price EUR113.45
EPS 3Y Cagr NM

Filgo to be filed in 2019; bullish conclusions from pre-NDA meeting

Filing with the FDA in the RA indication in 2019

Gilead announced that, following discussions with the FDA in the context of the pre-NDA meeting, it intends to file filgotinib in the rheumatoid arthritis (RA) indication in 2019. This announcement follows discussions based on the results from the FINCHes studies, as well as the ongoing MANTA trial.

Not sure yet what will be necessary to file

However, there is no mention of what would be necessary to file filgotinib. The timeline suggests that the 13-week results from the MANTA trial might be added to the dossier. Considering that the recruitment accelerated significantly in the past months with several centres opening in Asia and Eastern Europe, this seems a realistic scenario.

More aggressive approval timeline than our base case

This timeline of a filing in the course of the year is slightly more aggressive than our base case of a filing in early 2020. Should Gilead use its latest voucher for filgotinib in the RA indication - which remains our central scenario - this implies that filgotinib should be approved in H2 2020 at the latest.

As such, filgotinib should 1/ reach the US market c.9 months after the launch of AbbVie's upadacitinib which will not be able to claim superiority over adalimumab and 2/ be the only JAK approved at two doses which better fits into physicians' practice (cf. our [recent note on MANTA](#)).

Significant relief to the shares

The confirmation of a filing in 2019 should be a significant relief to GLPG shares - GILD to a lesser extent - as the FDA requirement for the full 24-week results from MANTA would have caused the FDA filing to slide into 2020, lowering the competitive profile of filgotinib. In H2 2019, GILD/GLPG should submit filgotinib in the RA indication with the FDA and in Europe (3Q 19).

While the unknown of MANTA is now behind us, we would expect investors focus to shift on the pipeline of GLPG, notably with GLPG1690 in phase III in IPF and GLPG1972 in phase II in KOA.

Market Data

Bloomberg / Reuters	GLPG BB/GLPG.BR
Market Cap.	EUR6,220m
E.V.	EUR4,933m
Free Float	65,6%
Avg. Daily volume (6m)	405.6
12m high / low	EUR113.6 / EUR75.6
Ytd Perf.	40.8%

EURM	12/18	12/19e	12/20e	12/21e
Sales	317.8	112.9	189.4	171.0
% Change		-64.5%	67.8%	-9.7%
EBITDA	NM	NM	NM	NM
% Change		ns	ns	ns
EBIT	-44.8	-181.8	-107.6	-75.4
% Change		NS	40.8%	30.0%
Net Income	-29.3	-177.8	-104.7	-72.8
% Change		NS	41.1%	30.4%
ROE	NM	NM	NM	NM

	12/18	12/19e	12/20e	12/21e
EV/Sales	15.5x	46.8x	28.5x	32.2x
EV/EBITDA	x	x	x	x
EV/EBIT	NS	NS	NS	NS
EPS	-0.56	-3.41	-2.01	-1.40
% change		NS	41.1%	30.4%
P/E	NM	NM	NM	NM
Div Yield	NM	NM	NM	NM

Next Catalyst : filgo H2 2019 EU and US filing

Last FV Change:

[2019-3-29, Filgotinib likely to FINCH a great share of the RA market](#)

Last Reports:

[2019-6-25, \(MANTA\) With or Without You](#)

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Distribution of stock ratings

BUY ratings 50,6%

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