

11th June 2019

GALAPAGOS

Healthcare
Biotech

BUY

Fair Value EUR140(+36%)
Share price EUR103.00
EPS 3Y Cagr NM

Fast recruitment provides GLPG with a major readout to look forward to in 2020

Fast recruitment: readout in H2 2020

Galapagos and partner Servier announced the completion of recruitment of the ROCCELLA phase II trial for GLPG1972 in knee osteoarthritis (KOA). The study recruited over 850 patients including more than 300 in the US across 41 active sites managed by Galapagos. While we initially expected the completion of recruitment later this year (Q3'19) the readout of the study should now occur in H2 2020 vs late 2020/early 2021 previously, hereby providing Galapagos with a major readout in 2020. This is important as we felt investors have been somewhat concerned about the lack of mid/late-stage clinical newsflow in 2020. As a reminder, the ISABELA 1 & 2 phase III trials in IPF should readout in 2021.

ROCCELLA phase II trial builds on encouraging early signals

GLPG1972 has the potential to be the first disease-modifying drug in KOA and showed a significant dose-dependent drop in ARGS levels at 30 days (marker for target engagement and proxy for cartilage degradation) in phase Ib, at the 100mgQD, 200mgQD and 300mgQD doses. In the phase II ROCCELLA, patients will be randomized to the same dose that was studied in phase Ib vs placebo over a 52w treatment course at the end of which the evolution in cartilage thickness will be measured by MRI (primary endpoint). We would pay attention to liver toxicity as one woman in the high dose group dropped out at day 15 of the phase Ib. This AE proved to be reversible.

High unmet medical need in KOA ...

The fast recruitment translates the high interest from patients in GLPG1972. There are currently no disease modifying drugs on the market with preferred options being relatively similar from early to late stage KOA i.e. NSAIDs and AI injections.

	Mild OA	Moderate OA	Severe OA
1st Line	- physical therapy - oral analgesics - topicals	- oral analgesics - topicals	- Opioids - IA injections
2nd Line	- NSAIDs - non-selective NSAIDs - COX-2 inhibitors	- NSAIDs - non-selective NSAIDs - COX-2 inhibitors	TREATMENT GAP
3rd Line	- Opioids - IA injections	- Opioids - IA injections	- Surgery (TKA)

Source: clinical guidelines, Bryan Garnier & Co.

... Supports EUR3bn peak sales (PoS of 30%)

We reiterate our EUR3bn peak sales for the compound (non-risk adj.) as well as our 30% PoS. GLPG1972 accounts for c.EUR5 of our Fair Value.

Galapagos retains all rights for the compound in the country. It remains eligible to high single-digit royalties in territories handled by Servier (i.e. OUS). Once the ROCCELLA phase II trial will readout, we believe that two - successful - phase III trials will be required by the FDA to be able to file GLPG1972 in the US.

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Market Data

Bloomberg / Reuters	GLPG BB/GLPG.BR
Market Cap.	EUR5,625m
E.V.	EUR4,478m
Free Float	65.6%
Avg. Daily volume (6m)	430.2
12m high / low	EUR111.2 / EUR75.6
Ytd Perf.	27.9%

EURM	12/17	12/18e	12/19e	12/20e
Sales	155.9	317.8	112.9	196.5
% Change			-64.5%	74.1%
EBITDA	NM	NM	NM	NM
% Change		ns	ns	ns
EBIT	-89.8	-44.8	-181.3	-98.7
% Change		50.1%	NS	45.6%
Net Income	-115.7	-29.3	-177.3	-95.7
% Change		74.7%	NS	46.0%
ROE	NM	NM	NM	NM

	12/17	12/18e	12/19e	12/20e
EV/Sales	28.7x	13.6x	41.5x	24.4x
EV/EBITDA	x	x	x	x
EV/EBIT	NS	NS	NS	NS
EPS	-2.33	-0.56	-3.40	-1.84
% change		75.9%	NS	46.0%
P/E	NM	NM	NM	NM
Div Yield	NM	NM	NM	NM

Next Catalyst: mid-2019, 52w FINCHes and update on FDA filing timeline

Last FV Change:

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

Last Reports:

[2019-4-26, No surprises in Q1'19 numbers; Newsflow to pick-up in H2'19](#)



BRYAN, GARNIER & CO

Morning Text

- Bullet

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