

Galapagos

Price EUR60.64

Filgotinib Phase III program now fully ready

Fair Value EUR64 (+6%)

BUY

Bloomberg	GLPG.BB
Reuters	GLPG.BR
12-month High / Low (EUR)	63.8 / 32.7
Market Cap (EURm)	2,800
Avg. 6m daily volume (000)	242.5

ANALYSIS

- Galapagos announced the completion of consultations with regulators for filgotinib in IBD. Hence the biotech's partner, GILEAD, should initiate shortly a phase III in Crohn's Disease (DIVERSITY; NCT02914561) as well as a phase IIb/III in Ulcerative Colitis (SELECTION). First patient-in expected in Q4 2016.
- While each study is expected to recruit about 1,300 patients, the SELECTION trial should include a futility analysis to comply with regulatory requirements to integrate a phase IIb as part of the program. Both the 100mg/QD and 200mg/QD will be evaluated in men and women with moderate to severe disease as a 2L treatment (after immunomodulator or anti-TNF or vedolizumab) over a 10 week treatment course with the possibility to enter a long-term extension study. We believe that the sweet spot for filgotinib in IBD would be for newly diagnosed patient's right after corticosteroids i.e. before anti-TNF.
- To note is that in the US, the FDA requested that male may be included in the 200mgQD dose group only if they failed at least one anti-TNF and vedolizumab. While we do not consider the toxicity in male reproductive organs as being an issue, a dedicated male testicular safety study will be included in the phase III program. We would not expect this safety trial to slow enrolment rate in the US as 1/ a large proportion of patients are women and 2/ the narrowed enrolment criteria this implies for the 200mgQD dose group should be lifted at the end of the safety trial. Recall that GLPG already conducted extensive pre-clinical studies and met the safety margin requested by the FDA.

VALUATION

- We reiterate our BUY rating and EUR64 fair value

NEXT CATALYSTS

- Q4 2016
 - Cystic Fibrosis program: GLPG1837 phase II results, GLPG2451 phase I results
 - Filgotinib phase II program: first patient-in in the DIVERSITY (CD) and SELECTION (UC) trials

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Distribution of stock ratings

BUY ratings 72%

NEUTRAL ratings 0%

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