FLASH NOTE

Company Update

Netherlands | Healthcare | Biotechnology

12 September 2018

Jefferies

Galapagos (GLPG NA)

FINCH a Cinch for Filgotinib; Bolsters Confidence in Multi-Blockbuster Potential

Key Takeaway

Filgotinib Phase III FINCH-2 arthritis data are positive, with efficacy on par or above competing JAKi's. Importantly safety is reassuring, with filgotinib's potentially superior safety profile a key differentiator, driving uptake despite likely being fourth to market. Success also de-risks the ongoing FINCH-1 and -3 trials, and provides positive read-through to ongoing Phase III IBD studies, cementing confidence in multi-blockbuster potential. Reiterate Buy.

Filgotinib data at the top-end of our expectations: The Phase III FINCH-2 trial evaluating filgotinib in rheumatoid arthritis (RA) patients post-biologics has met the primary endpoint, with both doses leading to statistically significant improvements in ACR20 at week-12 versus placebo. Filgotinib 100mg once-daily (QD) or 200mg QD resulted in an impressive placebo-adjusted ACR20 improvement of 26.4% and 34.9% at week-12, respectively (both $p<0.001$). Recall, we previously suggested that placebo-adjusted ACR20 20-25% for low dose and 25-30% for high dose should be considered a success given competitors' data. Both doses also led to statistically significant improvements in ACR50 (17% & 28%), ACR70 (8% & 15%), low disease activity DAS28-CRP$\leq$3.2 (22% & 25%) and clinical remission DAS28-CRP$\leq$2.6 (17% & 14%) at week-12, at the top-end or exceeding our expectations on a placebo-adjusted basis. All endpoints were also statistically significant at week-24 and again showed a clear dose-response. While we caution when comparing across clinical trials, these data are broadly comparable or above those reported for competitor oral JAK inhibitors, notably the higher 200mg QD filgotinib dose. FINCH-1 and -3 data during 1H19E could enable RA launches by YE20E with partner Gilead (GILD, $72, Buy), assuming the Phase II MANTA male testicular toxicity study reads-out successfully by 2H19E.

Safety reassuring: Filgotinib was generally well-tolerated, with treatment-emergent adverse events (AEs) and serious AEs mostly mild or moderate in severity. Importantly, there were no reports of deep vein thrombosis (DVT) or pulmonary embolism (PE), in keeping with our thesis that filgotinib could be best-in-class from a safety standpoint. There were also no deaths, malignancies, gastrointestinal perforations, or opportunistic infections. Two major adverse cardiovascular events occurred, a subarachnoid haemorrhage in the placebo group and a myocardial ischaemia in the low-dose filgotinib group. There was a non-serious retinal vein occlusion in the high-dose filgotinib group and two cases of uncomplicated herpes zoster in each active dose cohort. We believe filgotinib's high JAK1 selectivity could be differentiating, since it: (1) does not increase platelets, thus potentially less DVT risk; and, (2) does not decrease haemoglobin or lymphocyte levels, so potentially less risk of anaemia and infections. Since filgotinib is likely to be the fourth JAKi to market, a clean safety profile could help drive use.

Multi-blockbuster potential for filgotinib: We forecast $6bn WW peak sales, with $3bn in RA, $600m in Crohn's disease, $400m in ulcerative colitis, and a $2bn cumulative contribution for other indications, for c.€65 per share NPV with a 65% probability of success. Following the recent positive Phase II ankylosing spondylitis (TORTUGA study) data, results in Sjogren's syndrome, uveitis and forms of lupus could further confirm our view of the broad commercial potential.

Pipeline rightfully gaining attention: Phase III ISABELA studies of GLPG1690 in lung fibrosis (IPF) are expected to begin recruiting patients 2H18E. We forecast $850m WW '1690 peak sales after 2022E launch. The Phase II ROCCELLA trial of GLPG1972 in osteoarthritis and the Phase II PINTA trial of GLPG1205 in IPF will both also begin enrolling shortly. GLPG1972 is being examined as a unique MoA for the unmet need in osteoarthritis, with GLPG retaining all US rights.

BUY
Bloomberg BRU: GLPG NA
Price target €120.00
Price €88.92^

BUY
Bloomberg NASDAQ: GLPG
ADR Price target $140.00
ADR Price $102.74^

^Prior trading day's closing price unless otherwise noted.

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Company Description

Galapagos

Galapagos is a Belgian biotech company focusing on drug discovery using cells taken from patients with diseases of interest; typically musculoskeletal, CNS and inflammatory disorders plus orphan indications. The company's most advanced product is filgotinib (GLPG0634 a JAK1 inhibitor) is in Phase III for rheumatoid arthritis, Crohn's disease and ulcerative colitis partnered with Gilead. Galapagos also has a global alliance with AbbVie in cystic fibrosis. The company also has active collaborations with Servier and MorphoSys.

Company Valuation/Risks

Galapagos

Our Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for filgotinib, the cystic fibrosis alliance, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and MOR106 in atopic dermatitis, plus Net Cash. Risks include: (1) efficacy, safety, or regulatory setbacks; (2) need to execute future out-licensing and alliances; and (3) clinical trial failures.

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(Article 3(1)e and Article 7 of MAR)

Recommendation Published	September 12, 2018 , 01:57 ET.
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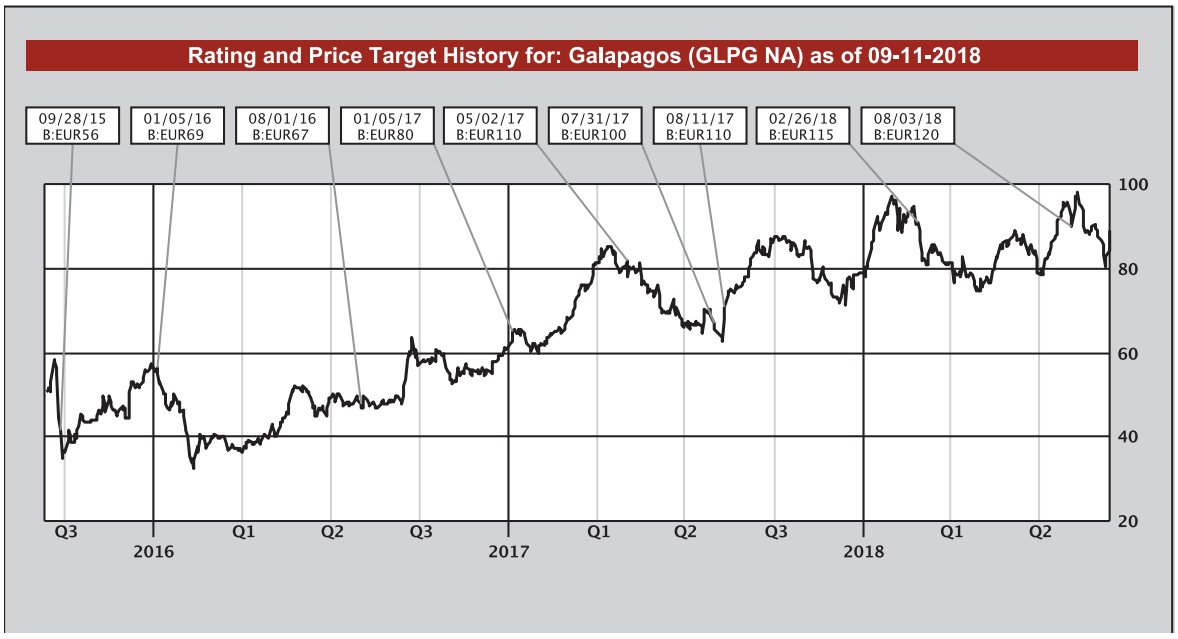

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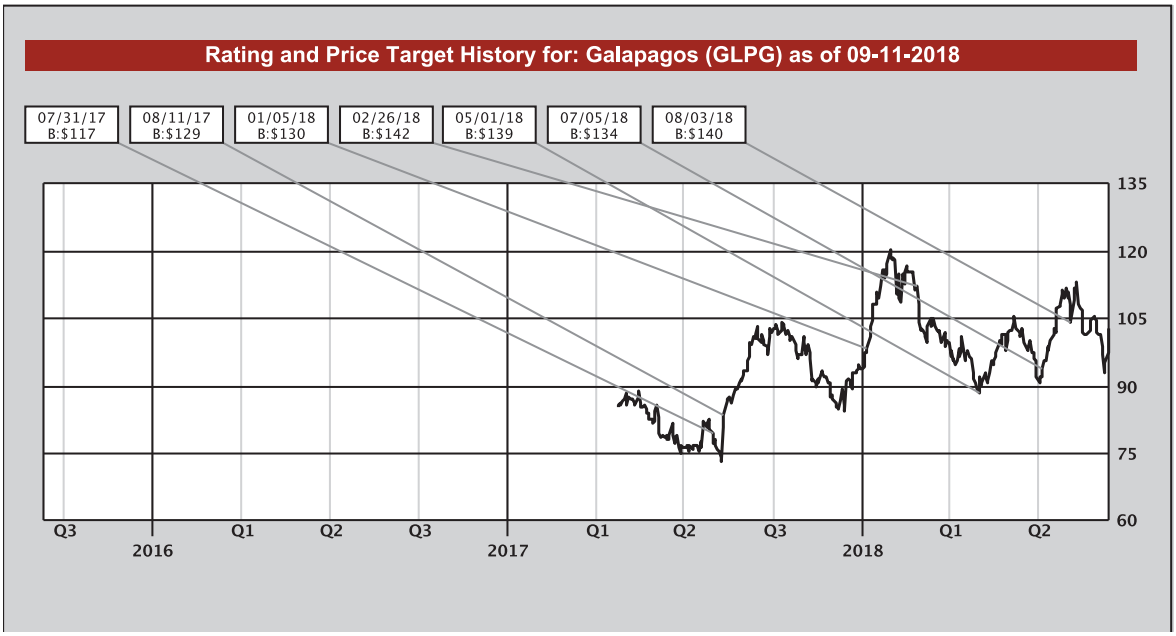

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