FLASH NOTE

Company Update

Netherlands | Healthcare | Biotechnology

6 September 2018

Jefferies

Galapagos (GLPG NA)

Positive Filgotinib AS Phase II; Safety OK on Closer Inspection

BUY
Bloomberg BRU: GLPG NA
Price target €120.00
Price €83.48^

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

EQUITY RESEARCH EUROPE

Key Takeaway

Impressive filgotinib Phase II efficacy in ankylosing spondylitis paves the way for Phase III. We expect the single DVT case may initially drive share price weakness today but importantly we understand this patient had an inherited risk of thrombosis (detail below). Focus is on the key upcoming filgotinib FINCH-2 Phase III arthritis data on which we remain optimistic efficacy will be in-line with other JAKi but believe safety could be a notable differentiator.

Positive filgotinib efficacy in AS: The Phase II TORTUGA study on filgotinib in ankylosing spondylitis (AS) met the primary endpoint of improved AS Disease Activity Score (ASDAS) at week-12 versus placebo, with -1.5 vs. -0.6 mean change from baseline ($p<0.0001$). The commonly used ASAS20 response rate was also statistically significant (76% vs. 40%, $p<0.0001$). Further details will be presented at a future clinical meeting. Acknowledging the usual caveats of comparing across clinical trials we note Xeljanz (tofacitinib) Phase II ASAS20 at week-12 were 81% 5mg bid ($p<0.001$) and 56% 10mg bid (p n.s.) vs. 41% placebo, at best comparable to filgotinib. We expect Galapagos and partner Gilead (GILD, $75, Buy) to initiate Phase III in AS next year.

Safety generally as expected but DVT required clarification: Adverse events were generally mild-moderate and similar to placebo, with no new safety signals and consistent lab changes to prior trials. The case of non-serious deep vein thrombosis (DVT) in a patient randomised to filgotinib will likely initially raise widespread concern, given DVT is a well-documented risk for competing JAKi Olumiant (baricitinib) and has been scrutinised for AbbVie's (ABBV, $95, Buy) upadacitinib. Importantly we understand this patient had an inherited risk of thrombosis (Factor V Leiden gene mutation) and the DVT occurred in the follow-up period post-treatment, hence was later assessed to not be treatment-related. There was also one treatment-emergent serious pneumonia on filgotinib, treated with hospital antibiotics; not unexpected as for all immuno-modulating drugs. No deaths, malignancies, hepatic events, opportunistic infections, or Herpes zoster cases were observed.

Upcoming filgotinib data could demonstrate differentiated profile: FINCH-2 data evaluating filgotinib in rheumatoid arthritis (RA) patients post-biologics is expected imminently (preview here), and is the first of three Phase III filgotinib studies in RA. Safety will be a focus, notably thrombotic events for which we remain optimistic filgotinib could be best-in-class. We think 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. For efficacy by the ACR20 primary endpoint we view placebo-adjusted 20-25% for low dose and 25-30% for high dose to be positive. FINCH-1 and -3 data during 2019E could enable RA launches by YE20E with partner Gilead, assuming the Phase II MANTA male testicular toxicity study reads-out 2H19E.

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. Beyond AS, Phase II results in Sjogren's syndrome, uveitis and forms of lupus, could further confirm our view of the broad commercial potential.

CF remains acutely in focus: GLPG is reviewing the future of its cystic fibrosis (CF) alliance with AbbVie after the pharma decided not to pursue the second triple, which we believe triggered a breakdown in the relationship. Initial Phase Ib FALCON data from the first triple are expected late-3Q18E (preview here).

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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.

AbbVie

Our $110 PT is supported by DCF, PE and PEG-relative valuations. Risks: Humira; R&D; reimbursement; M&A.

Gilead Sciences, Inc.

Our $95 PT is based on a pipeline-adjusted DCF and 16x our 2019 EPS estimate. Risks: competition, pipeline disappointments, and worse-than-expected sales.

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Investment Recommendation Record

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

Recommendation Published	September 6, 2018 , 02:23 ET.
Recommendation Distributed	September 6, 2018 , 02:23 ET.

Company Specific Disclosures

Steven DeSanctis owns shares of AbbVie Inc. common shares.

Jefferies LLC is acting as a financial advisor to Kite Pharma (KITE) on the sale of the company to Gilead Sciences (GILD).

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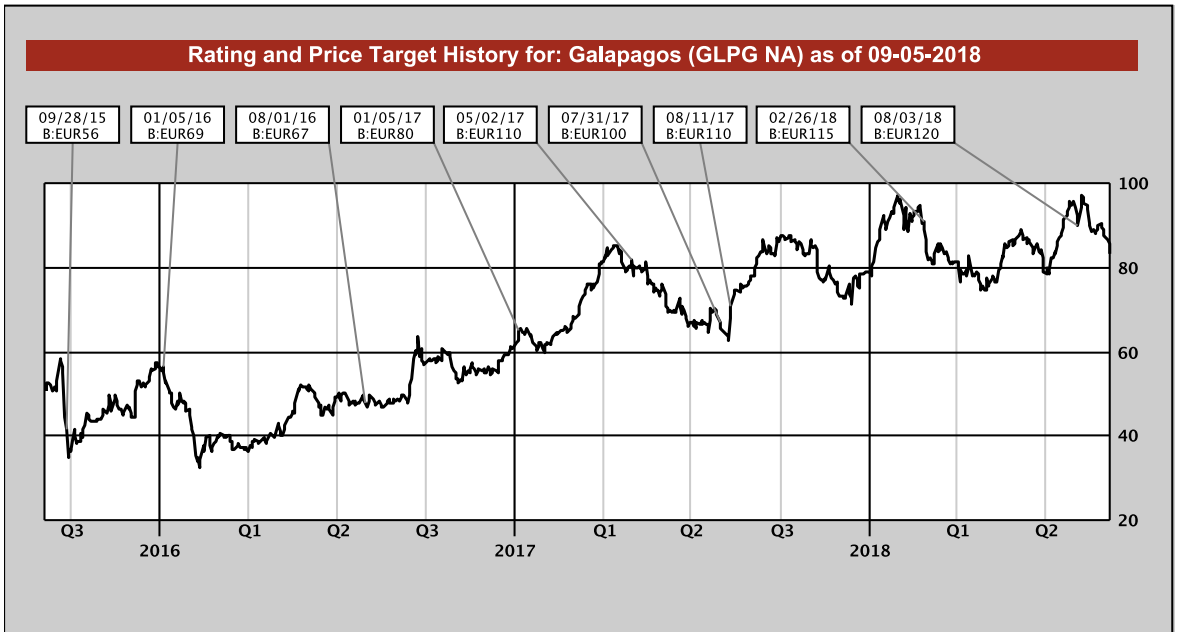
- Gilead Sciences, Inc. (GILD: $74.53, BUY)



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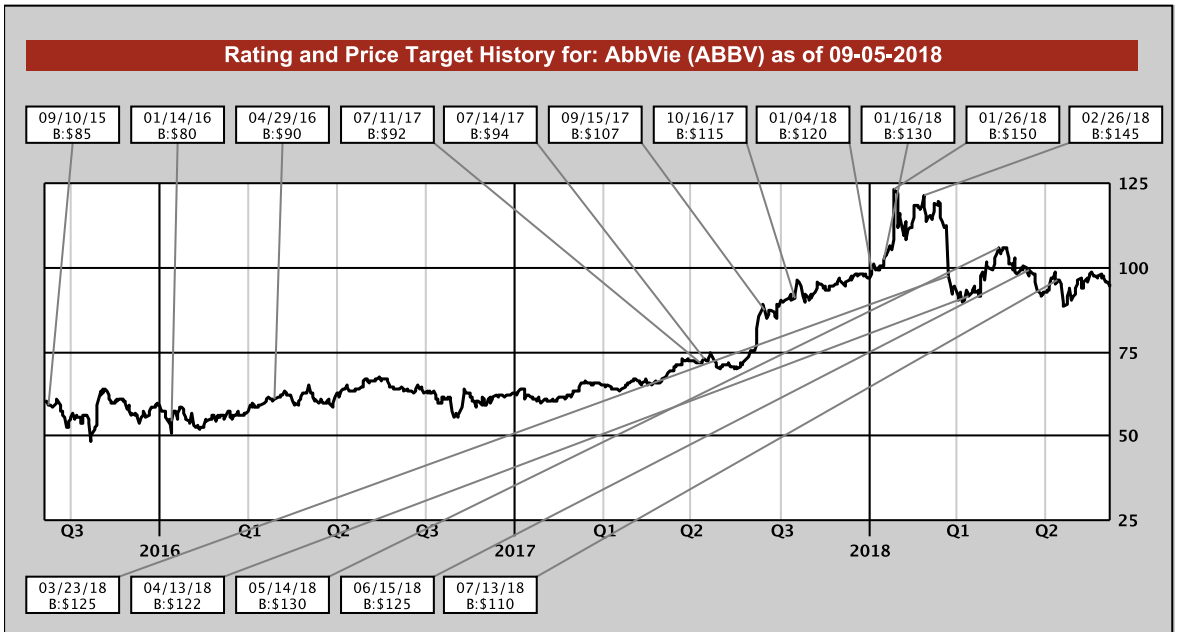

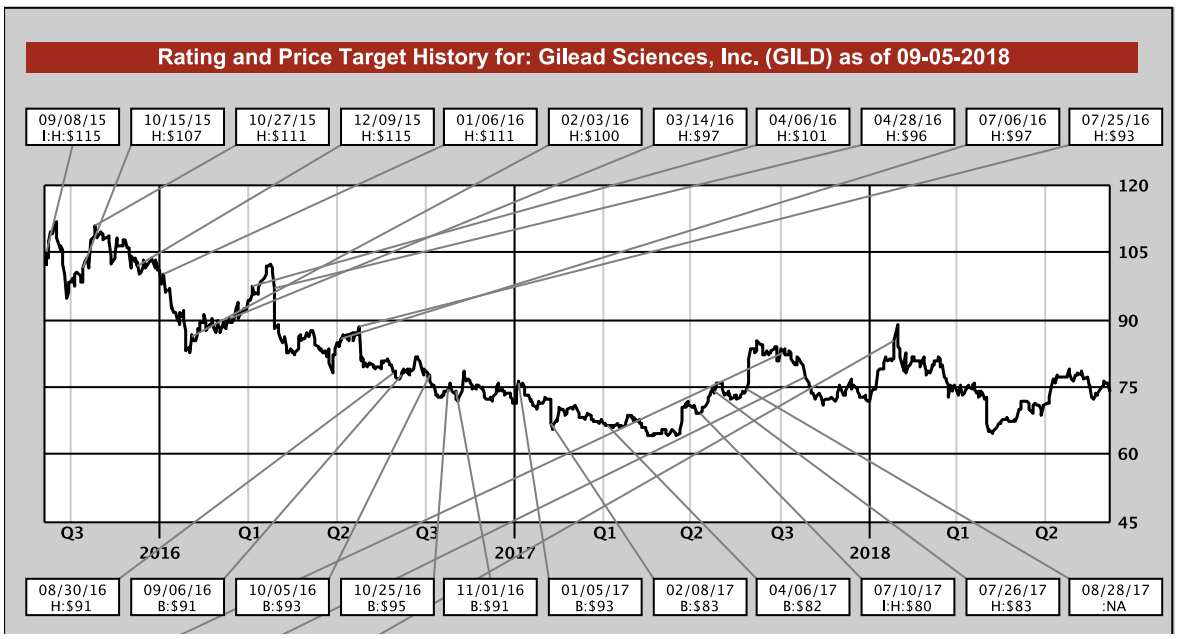

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