Galapagos

Positive Phase III Filgotinib Ulcerative Colitis Data Underpin Blockbuster Hope

21 May 2020

Key Takeaway

Overall filgotinib ulcerative colitis Phase III efficacy data are positive in our view, with high dose maintenance data above our expected efficacy bar, albeit somewhat disappointing the lower dose missed significance for induction. Safety looks broadly consistent with prior filgotinib trials, notably with low rates of venous thromboembolism and serious infections. Next key catalyst is likely assured filgotinib arthritis (RA) approvals from 3Q20E.

Compelling high dose efficacy, albeit disappointing low dose induction miss: High-dose JAK-1 selective filgotinib 200mg met both co-primary endpoints in the Phase III SELECTION trial in ulcerative colitis, improving rates of clinical remission at week-10 induction and week-58 maintenance vs placebo, whilst the lower 100mg dose met only the maintenance endpoint. Although induction efficacy is toward the lower end of our c.10%-15% expectations, we are encouraged by compelling maintenance data which are just above the c.20%-25% efficacy bar outlined in our preview, particularly given over half of patients were biologic-exposed patients and c.26% had been treated with two different classes of biologics. Filgotinib led to placebo-adjusted improvements of:

- **Week-10 induction biologic-naive:** 10.8% on 200mg (p=0.0157); 100mg not disclosed
- **Week-10 induction biologic-exposed:** 7.3% on 200mg (p=0.0103); 100mg not disclosed
- **Week-58 maintenance biologic-naive and biologic-exposed:** 26% on 200mg (p<0.0001); 10.3% on 100mg (p=0.0420)

Recall, we previously outlined data comparisons with other biologics and PFE's Xeljanz (JAK1-3), are challenging given the variable degree of biologic-exposed patients, plus different time points and definitions of clinical remission used. Encouragingly, these data suggest filgotinib's efficacy is comparable to Xeljanz, but with a potentially best-in-class safety profile, also assuming the ongoing MANTA studies confirm safety of the higher 200mg dose in males.

Safety looks consistent with prior trials: Overall we believe safety is broadly consistent with prior filgotinib trials. Importantly rates of pulmonary embolism and venous thrombosis were reported as "low", as were rates of serious infections, herpes zoster, and gastrointestinal perforation. Incidence of serious adverse events (SAEs) were:

- **Week-10 induction biologic-naive:** 1.2% on 200 mg; 4.7% on 100 mg; 2.9% on placebo
- **Week-10 induction biologic-exposed:** 7.3% on 200 mg; 5.3% on 100 mg; 6.3% on placebo
- **Week-58 maintenance:** 4.5% on 200 mg vs 0% placebo; 4.5% on 100 mg vs 7.7% placebo

Neither of two deaths on 200mg filgotinib in the maintenance trial seems concerning, in our view, as they were both unrelated to study drug, with one asthma exacerbation

FLASH NOTE

Netherlands | Biotechnology

RATING	**BUY**
TICKER	**GLPG NA**
PRICE	**€201.50^**
PRICE TARGET (PT)	**€210.00**
MARKET CAP	**€13.1B / $14.3B**

RATING	**BUY**
TICKER	**GLPG**
PRICE	**$221.27^**
PRICE TARGET (PT)	**$232.00**
MARKET CAP	**€13.1B / $14.3B**

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

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in a patient with pre-existing asthma, and one left ventricular heart failure in a patient with pre-existing atherosclerosis.

RA approvals expected from 3Q20E: Approval of both filgotinib doses for arthritis could be differentiating versus competitors. We forecast $6bn WW peak sales for filgotinib, with $3bn in RA, $600m in Crohn's disease, $400m in UC, and a $2bn cumulative contribution for other indications, combined worth c.€94/share (c.45% of NPVs) at 95% probability.

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, a JAK1 inhibitor, which has completed Phase III for rheumatoid arthritis and is also in development for Crohn's disease and ulcerative colitis partnered with Gilead. The company has a broad R&D collaboration with Gilead and also has active collaborations with Servier and MorphoSys.

Company Valuation/Risks

Galapagos

Our Price Target is based on a sum-of-the-parts valuation largley comprising probability-adjusted NPVs for filgotinib, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and Toledo in autoimmune disorders, plus Net Cash. Risks include: (1) regulatory setbacks for filgotinib; (2) upcoming late-stage pipeline catalysts are high risk; and (3) clinical trial failures.

Gilead Sciences, Inc.

Our $97 PT is based on our view that GILD remains a cheap and low-expectation story that is getting better and can achieve even a15 multiple on 2021 earnings, which is in line with pharma peers. Risks: competition, pipeline disappointments, and worse-than-expected sales.

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

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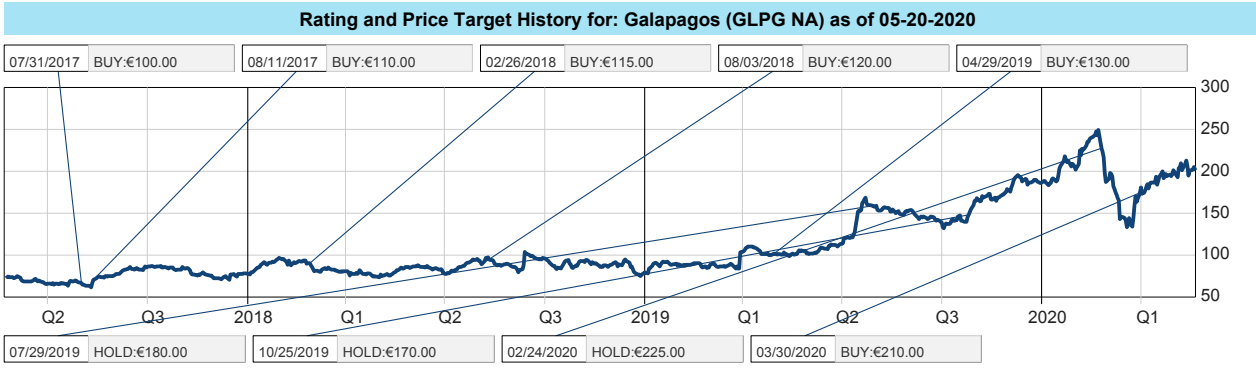

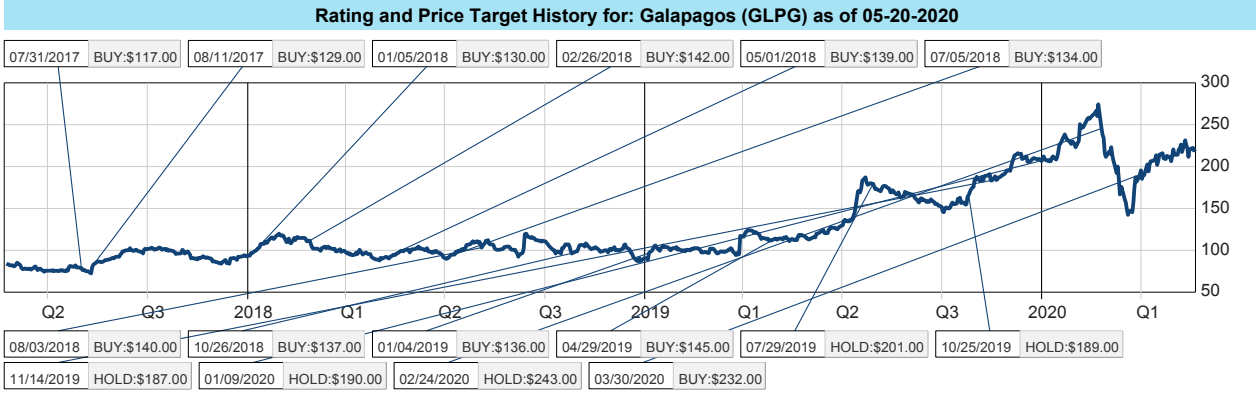

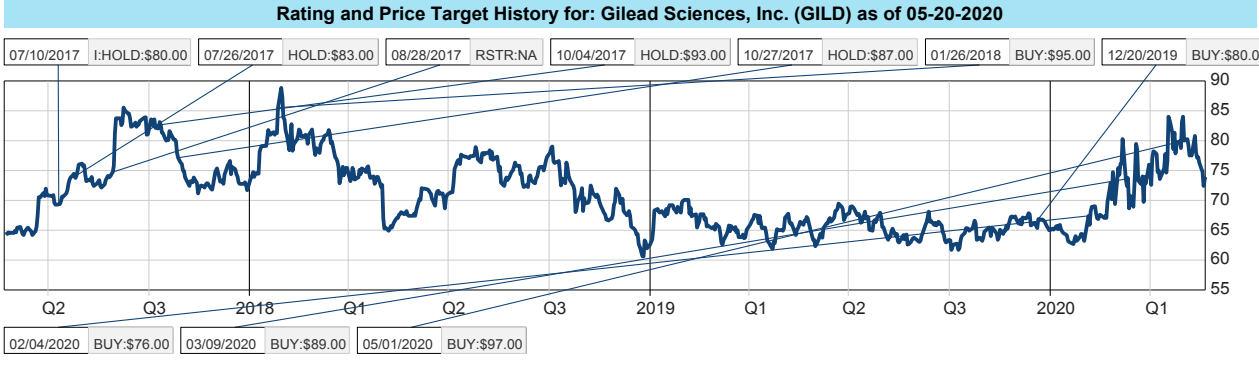

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Distribution of Ratings						
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	Count	Percent	Count	Percent	Count	Percent
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