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EQUITY RESEARCH

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■ Biotechnology

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QUICK TAKE: INDUSTRY UPDATE

FILGOTINIB HITS IN UC PH IIB/III, THOUGH DATA ON LOWER END OF EXPECTATIONS

THE COWEN INSIGHT

GILD/GLPG announced positive results from the Ph. IIb/III study of filgotinib in the treatment of UC. Filgotinib continues to look safe and effective. The 10.8% placebo-adjusted increase in clinical remission at wk 10 is comparable to data generated by PFE's Xeljanz, though below that demonstrated for ABBV's Rinvoq, and likely on the lower end of investor expectations. Remain (1) on GILD and GLPG.

Our Take: Results Likely To Support Approval And Adoption...

With filgotinib continuing to appear safe and well tolerated, and with its 200mg dose hitting the primary endpoints of the trial's induction and maintenance phases, we think the results are sufficiently strong to support licensure and drive adoption.

We think UC could be a meaningful revenue opportunity. We estimate that in the U.S. there are 400K moderate-to-severe UC patients, of whom 90K have failed conventional therapy and an anti-TNF. This implies a market oppy of $4B+ for filgotinib and the other JAKs. We estimate that Xeljanz is currently annualizing at approx. $150MM in UC, meaning there remains much potential for growth of the JAK class.

...But Perhaps On The Lower End Of Investor Expectations.

Nonetheless, based on the data produced by Xeljanz and Rinvoq in UC, investors had expected that filgotinib's Ph. II/III would succeed. Many were hopeful that filgotinib would produce a "best in class" profile in UC that is better than, or at least similar to, Rinvoq. Filgotinib's data did not quite reach these expectations.

Admittedly cross-trial comparisons are complicated by variations in endpoints and enrolled patients. Nonetheless, based on the available data, the results generated by 200mg QD filgotinib appear in line with those generated by Xeljanz in its Ph. III OCTAVE program, but somewhat below those produced by Rinvoq in its Ph. IIb program. Also, the lower 100mg QD dose of filgotinib failed to differentiate from placebo in the induction portion.

There are many caveats to the cross-trial comparisons between filgotinib, Xeljanz, and Rinvoq. It could be reasonably argued that filgotinib's trial enrolled a more refractory population than Xeljanz since there were no patients who had prior exposure to Entyvio in Xeljanz's pivotal program, while in filgotinib's 51% of patients had prior exposure to both TNF and integrin antagonists. Though the population in Rinvoq's Ph IIb appears similar to filgotinib (Rinvoq enrolled 44% of patients with prior exposure to a TNF and integrin antagonists), it is fair to note that efficacy data often degrades from Ph II to Ph III so Rinvoq's data may not hold up in future studies.

Clearly, more will be learned about filgotinib's competitive position. But we suspect the data fell a bit short of the expectations of those who anticipated a clear "best in class" profile.

Specifically, in the induction phase of filgotinib's study, placebo-adjusted clinical remission rates was 7.3% in biologic-experienced patients treated with 200mg QD filgotinib. This is similar to the 9% and 12% remission rates in patients with prior TNF failure treated with 10mg BID tofacitinib in the Phase III OCTAVE-1 and -2 induction trials, respectively.

Similarly, placebo-adjusted clinical remission rates were 10.8% for biologic-naïve patients treated with 200mg QD filgotinib vs. 10% and 14% in patients without prior TNF failure treated with 10mg BID tofacitinib in the Phase III OCTAVE-1 and-2 induction trials, respectively.

It is encouraging to see that, like Xeljanz, filgotinib appears to have demonstrated robust efficacy in patients with prior biologic exposure, which our consultants indicate is an important differentiating factor of JAK inhibitors in this indication.

Though efficacy data for filgotinib at the 200mg QD dose look similar to Xeljanz, the data are somewhat weaker than those generated by the higher doses of Rinvoq in the Phase IIb U-ACHIEVE induction study. Admittedly patient numbers are relatively small in the Rinvoq study, and efficacy data often gets worse from Ph. II to Ph. III. Nonetheless, 45mg QD upadacitinib led to placebo-adjusted clinical remission rates of 12% (n=5/42) in patients with inadequate response to biologics (Bio-IR) and 43% (n=6/14) in non-Bio-IR patients.

Placebo-adjusted remission rates continue to look similar to Xeljanz with maintenance dosing. At 58 weeks, the placebo-adjusted clinical remission rate was 26.0% in patients treated with 200mg QD filgotinib vs. 23.2% and 29.5% at 52 weeks in patients treated with tofacitinib 5mg BID and tofacitinib 10mg BID, respectively, in the OCTAVE-Sustain trial.

Filgotinib's safety appears acceptable. A full evaluation is not possible without the release of the detailed data. However, as there was no imbalance in serious infections, herpes zoster, venous thrombosis, pulmonary embolism, or GI perforations, the top-line results suggest that filgotinib's safety profile is very good. There were, two deaths in the 200mg QD filgotinib arm (one due to an asthma exacerbation and the other due to left ventricular heart failure), though neither were considered (or appear to be) related to study drug.

The News: The Ph IIb/III SELECTION study randomized patients with moderate-to-severe ulcerative colitis (UC) 2:2:1 to receive filgotinib 200mg, 100mg, or placebo for 10 weeks in two induction studies with n=659 patients that were biologic-naive and n=689 patients that were biologic-experienced. Those that had clinical remission or response at that time were re-randomized 2:1 to their induction dose of filgotinib or placebo and treated through week 58. The 200mg filgotinib dose met the primary endpoint of clinical remission during the induction (10 weeks) and maintenance (58 weeks) phases of the study, while the 100mg filgotinib dose only met the primary endpoint during the maintenance portion of the trial.

In biologic-naive patients, 26.1% of those treated with 200mg filgotinib achieved clinical remission vs. 15.3% of placebo-treated patients (p=0.0157). In biologic-experienced patients, 11.5% of those treated with 200mg filgotinib were in clinical remission at week 10 vs. 4.2% of those treated with placebo (p=0.0103).

A total of n=558 patients were randomized into the maintenance trial. At week 58, 37.2% of patients treated with filgotinib 200 mg (both biologic naive and experienced) achieved clinical remission vs. 11.2% of placebo-treated patients (p<0.0001). In those receiving filgotinib 100mg, 23.8% achieved clinical remission at week 58 vs. 13.5% of matched placebo patients (p=0.0420).

Filgotinib's safety profile continues to look acceptable with SAEs similarly distributed across treatment and placebo cohorts during the induction portion of the study for biologic-naïve patients (1.2%, 200mg; 4.7%, 100mg; 2.9%, placebo) and biologic-experienced patients (7.3%, 200mg; 5.3%, 100mg; 6.3%, placebo). For patients receiving 200mg of filgotinib in the extension, 4.5% had SAEs vs. 0.0% for matched placebo patients. For patients receiving 100mg of filgotinib in the extension, 4.5% had SAEs vs. 7.7% for matched placebo patients. During the maintenance portion of the study, there were two deaths in the 200mg filgotinib cohort, one due to asthma exacerbation and another due to heart failure. Both patients had pre-existing conditions and neither event was deemed related to filgotinib treatment. GILD/GLPG indicates that rates of serious infections, herpes zoster, venous thrombosis, pulmonary embolism, and GI perforation were low and comparable across treatment groups. Full safety detail including rates of specific AEs and SAEs in patients treated with filgotinib vs. placebo will be helpful in determining the drug's potential and potential differentiated safety profile.

Full data will be presented at a future scientific meeting.

VALUATION METHODOLOGY AND RISKS

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

ADDENDUM

Stocks Mentioned In Important Disclosures

Ticker	Company Name
GLPG	Galapagos NV (ADR)
GILD	Gilead Sciences

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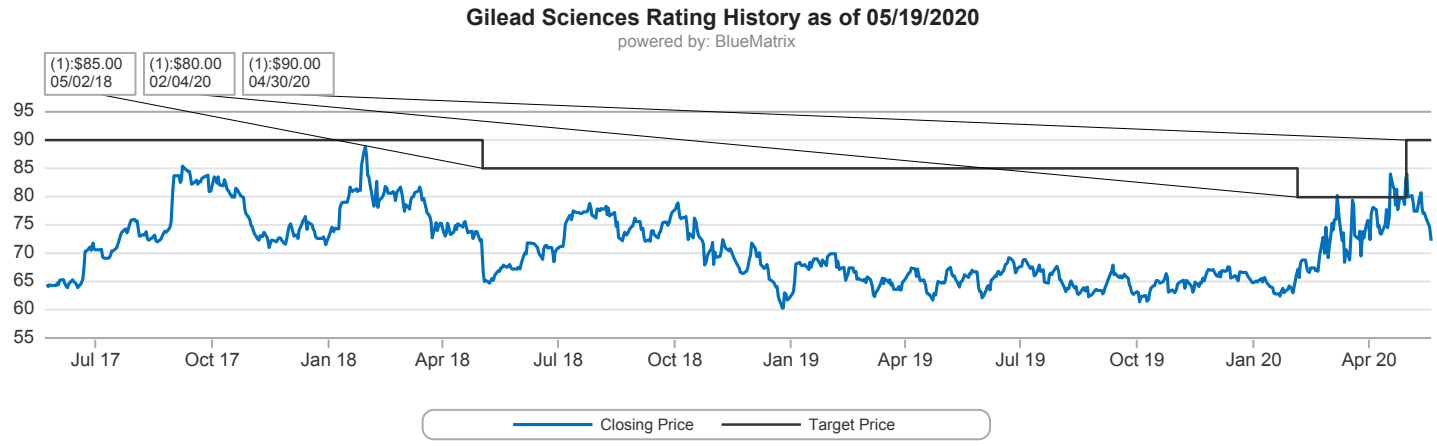

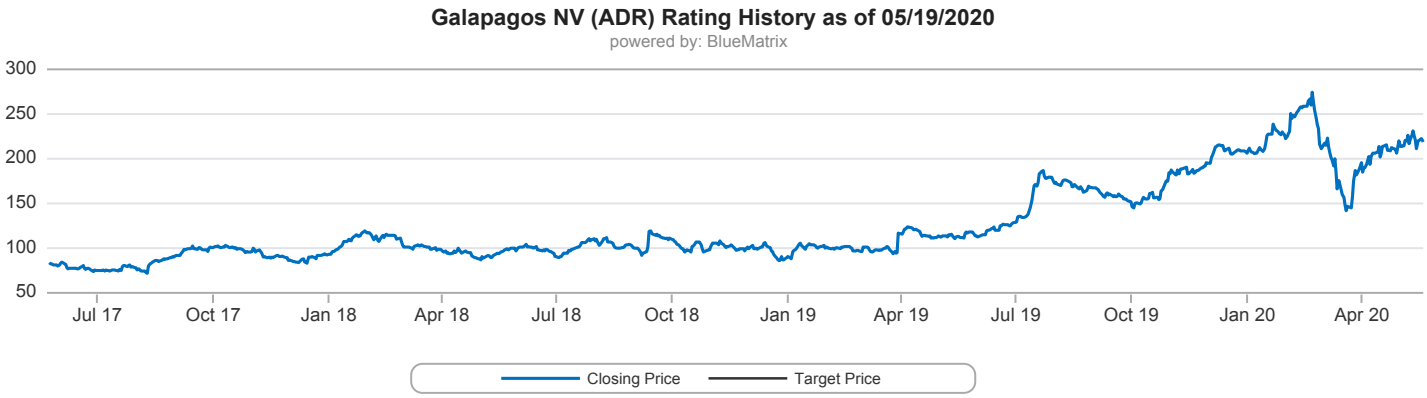

Initiated Coverage - 06/08/2015 - Rating Outperform

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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