EQUITY RESEARCH

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GLPG/GILD: Jyseleca Jibes With CHMP; What We Gleaned From Today's EU Filgotinib Opinion

This morning the CHMP issued a positive recommendation for potential approval of filgotinib (now called Jyseleca); the timing and action is in line with our expectations. Recall the EMA typically issues corresponding approval within 60 days.

The language within the opinion is relatively unremarkable and generally comparable to that of key competitor Rinvoq (ABBV)-- with both 100mg and 200mg doses recommended for approval, listed common side effects benign, the described SAE being serious infections, and the indication being for mod-severe inadequate DMARD responder adults with RA.

EMA has tended to be more lenient on JAK indications/labeling vs U.S. with respect to dosing, TE events, and had not been as concerned regarding potential filgotinib-related testicular tox, so we do not see much meaningful readthrough to some of the outstanding questions that could impact its potential label in the U.S. We continue to expect the U.S. label to (1) have a class boxed warning on TE events (though believe filg has lower risk among JAK inhibitors which GILD/GLPG could highlight); (2) likely include both 200mg and 100mg doses -- though we are keeping an eye on whether slight dose related death imbalance might impact this (200mg will be critical for competitiveness in our view); (3) unclear if it would receive monotherapy indication in U.S. (given the ACR20 data from FINCH-3) as Rinvoq has-- though we believe this is unlikely to be commercially meaningful either way, as monotherapy is rarely used.

We continue to see $1.6B worldwide out-year sales opportunity for filg in RA, with upside in IBD and psoriatic arthritis (despite what appears to be missed opportunity in atopic dermatitis); we believe this opportunity is already baked into GLPG valuation but underappreciated in GILD's shares.

Companies mentioned

Galapagos NV (NASDAQ: GLPG US; $200.40; Sector Perform)
Gilead Sciences, Inc. (NASDAQ: GILD US; $75.56; Outperform)

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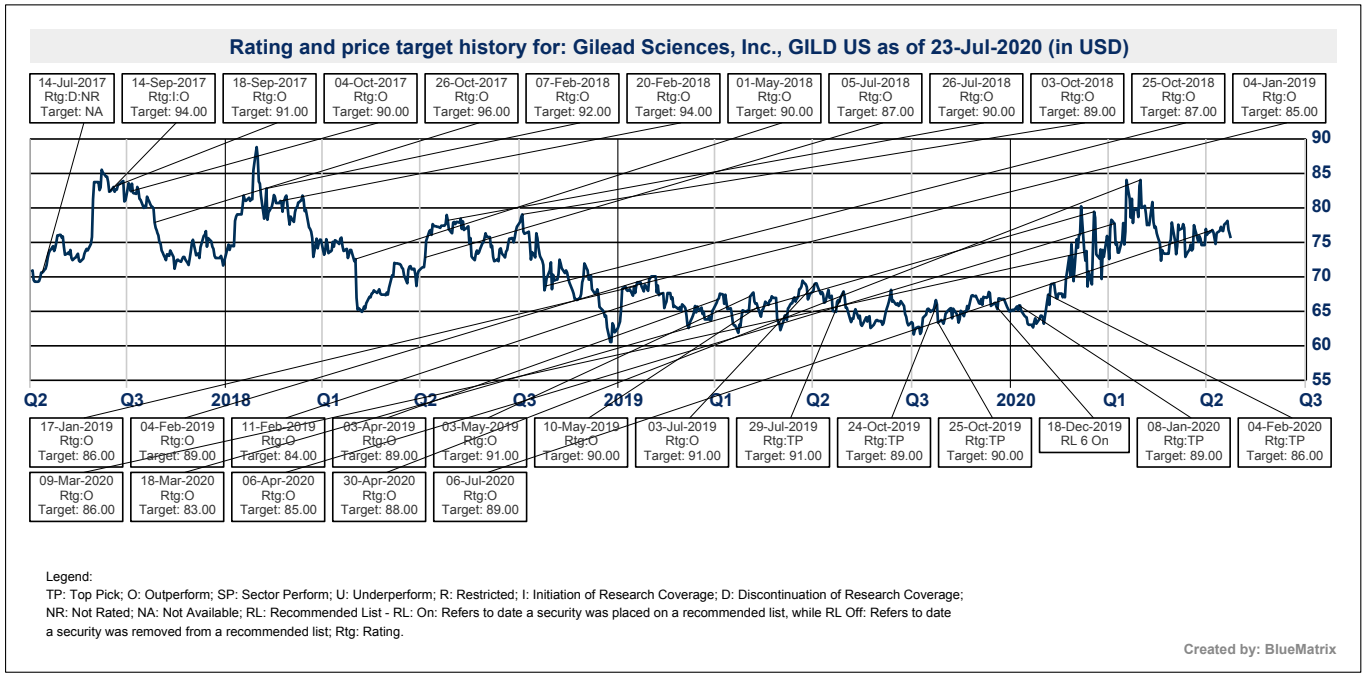

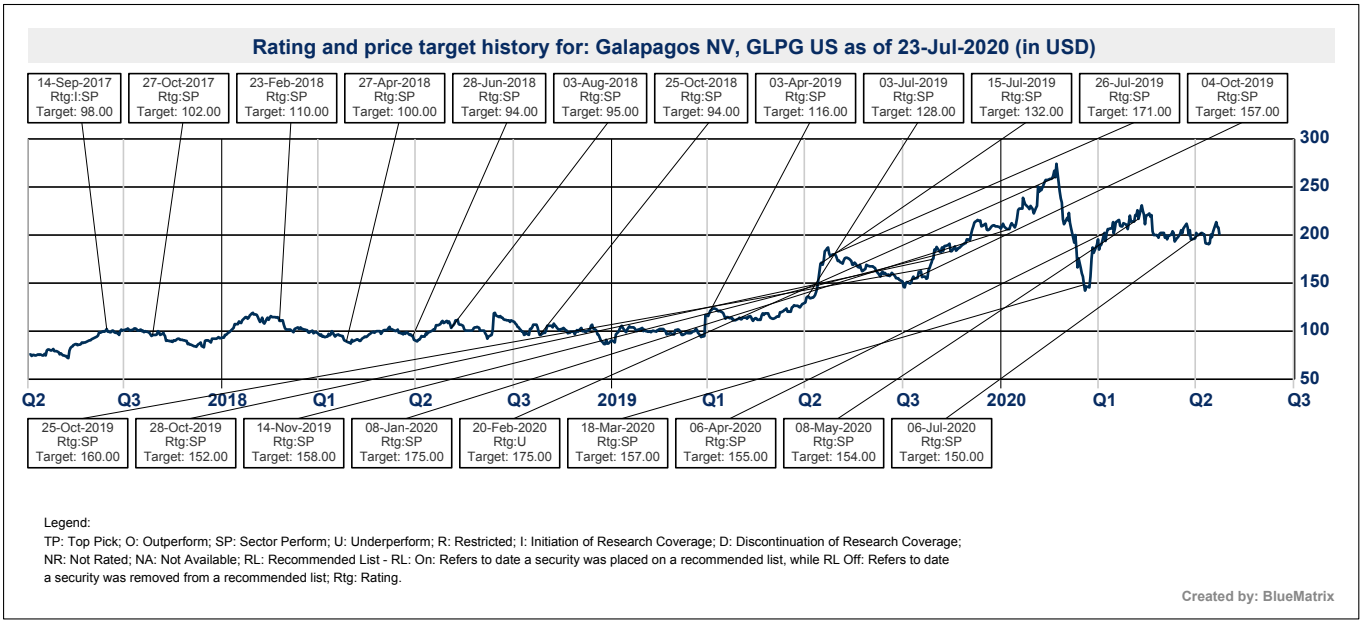

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Galapagos NV

Valuation

Our $150 price target is derived from a DCF analysis of the base business with a 10% discount rate and 2.7% terminal growth rate. This valuation supports our Sector Perform rating.

Risks to rating and price target

Risks include significantly greater/less than expected uptake for filgotinib in RA, potential BD activity, and better/worse than expected clinical data for ’1690 in IPF, Toledo compounds in inflammatory disease, and/or ’1972 in osteoarthritis, and lingering or expanding impact of COVID-19 on clinical development activities.

Gilead Sciences, Inc.

Valuation

Our $89 price target is derived via a DCF analysis, with an 8.9% discount rate and a 3% terminal growth rate off 2029E (post-TAF generic). Our price target supports our Outperform rating.

Risks to rating and price target

Risks inherent to GILD’s business include generic HIV entrants, competition in HCV, pricing pressure, commercial and scientific complexities of cellular CAR-T therapies, and efficacy and safety risk for pipeline products such as filgotinib. More systemically, GILD could also be negatively impacted by macro effects of an economic downturn, or impacts to GILD’s workforce, related to COVID-19.

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