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March 28, 2019

GILD/GLPG: Strong Filg Ph.III Data Supports Approvability, Though Competition Fierce

Ph.III FINCH 1 and 3 data reported this evening for filgotinib in RA show clear efficacy and most notably an extremely clean safety profile, which we believe significantly de-risk the program and clearly support approvability. Cross-trial comparisons that investors (and physicians) will inevitably make, however, do suggest efficacy across the board - even at the higher dose - looks less impressive vs. ABBV's further-ahead competitive Jak1 inhibitor upadacitinib, though filgotinib's safety may be even cleaner. Filing in key U.S. market still depends on ongoing MANTA study, but assuming this is clean, we see a high likelihood filgotinib reaches the market though there could be some debate over its exact place in the competitive landscape. We expect upside for GILD, who receives little credit for their pipeline, and for GLPG, though for the latter we believe some optimism was already baked in.

Efficacy looks robust... In FINCH 1's more "traditional" MTX-inadequate responders 200mg filgotinib looked moderately better than Humira and superior on the important DAS28 remission endpoint, while 100mg looked generally comparable to Humira; both were significantly better than MTX alone (see Exhibits on following pages). In the FINCH 3 study of treatment-naive patients, both 200mg and 100mg filgotinib + MTX were superior to MTX alone on symptomatic endpoints, though not on structural progression (likely because these patients were too early-stage to meaningfully progress); filgotinib monotherapy did hit on radiographic progression, but we believe is not likely to be taken forward since it missed on the ACR20 primary endpoint (likely owing to "catch-up" effect of MTX over the longer 24wk endpoint).

...but looks to fall somewhat short of what ABBV's upadacitinib has shown in ph.III. With the caveats of comparing across studies, we note that when comparing FINCH 1 to ABBV's SELECT-COMPARE study, both placebo- and Humira-adjusted benefits at 12 weeks - even at the higher filgotinib dose - look slightly less robust than ABBV's go-forward 15mg upa regimen. Similarly, for the SELECT-EARLY upa study in naive patients, comparable to FINCH 3, benefits of filgotinib added to MTX over MTX alone looked to be less robust than the go-forward upa 15mg dose administered as monotherapy. This could put filgotinib, which will also be later to market, at a modest commercial disadvantage on the efficacy side, though comparing the populations across the studies will be important to fully gauge any differences, such apparent differences could even out over time, many other considerations (safety - where filgotinib looks incrementally better, tolerability, access) will likely impact relative market share, and RA pts tend to switch among therapies anyway.

Safety looked as good as could have been hoped. Across the two ph.III's, there were generally no differences in VTE events, MACE events, herpes zoster, or serious infections vs. most controls. The companies also provided a press release with combined 24-week safety data from the full ph.III FINCH program showing no signal of dose dependence for any of the major AE categories of focus for this class (vs. ABBV's upa which showed hints of some dose-dependent AE signals albeit at low rates), and also noted improvements in hemoglobin and lipids, and reduction in platelets. We note that out of >2,000 total patients treated with filgotinib in ph.III, only 1 experienced a DVT or PE vs. 3 out of ~1,000 for the placebo/csDMARD group. We believe this should provide comfort to the FDA that Jak1 selectivity indeed is associated with a lower risk of thromboembolic events and should make potential approval relatively uncontroversial, pending the results of the ongoing MANTA testicular toxicity study.

We see filgotinib in RA as a potential $1.5B (~$1.1B GILD/$0.4B GLPG) unadjusted opportunity if ultimately approved, where lack of a safety signal could enable add'l adoption. *Continued on next page...*

Disseminated: Mar 28, 2019 20:46ET; Produced: Mar 28, 2019 20:46ET

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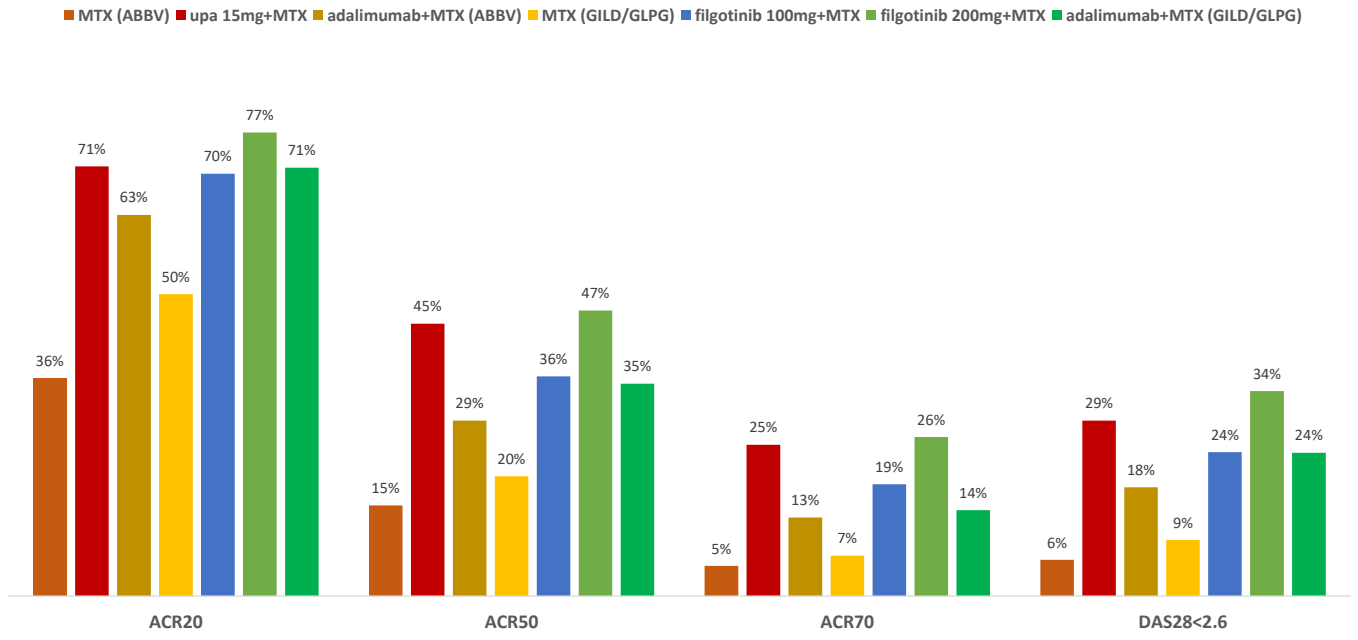
We see filgotinib in RA as a potential $1.5B (~$1.1B GILD/$0.4B GLPG) unadjusted opportunity if ultimately approved, where lack of a safety signal could enable add'l adoption. We currently est. a 2021 approval for filgotinib, given need for add'l MANTA data accumulation, which we assume will place filgotinib as the fourth Jak market entrant in RA. We believe the agent's clean safety may help offset the lack of monotherapy superiority over MTX and slightly lower relative efficacy vs. upa (albeit higher absolute). Given potential for filgotinib to be second-to-market JAK in UC and first in CD, we view IBD as the more substantial long-term opportunity at an unadjusted $4B. Overall, we see filgotinib as providing $5.5B unadjusted out-year revenues (~$4B GILD/$1.5B GLPG), currently adjusted to 70% in RA, 65% in UC, and 55% in CD.

Exhibit 1: FINCH 1 and SELECT-COMPARE efficacy data (unadjusted; 12 weeks)



Source: Company reports

Exhibit 2: FINCH 1 and SELECT-COMPARE efficacy data (MTX-adjusted; 12 weeks)

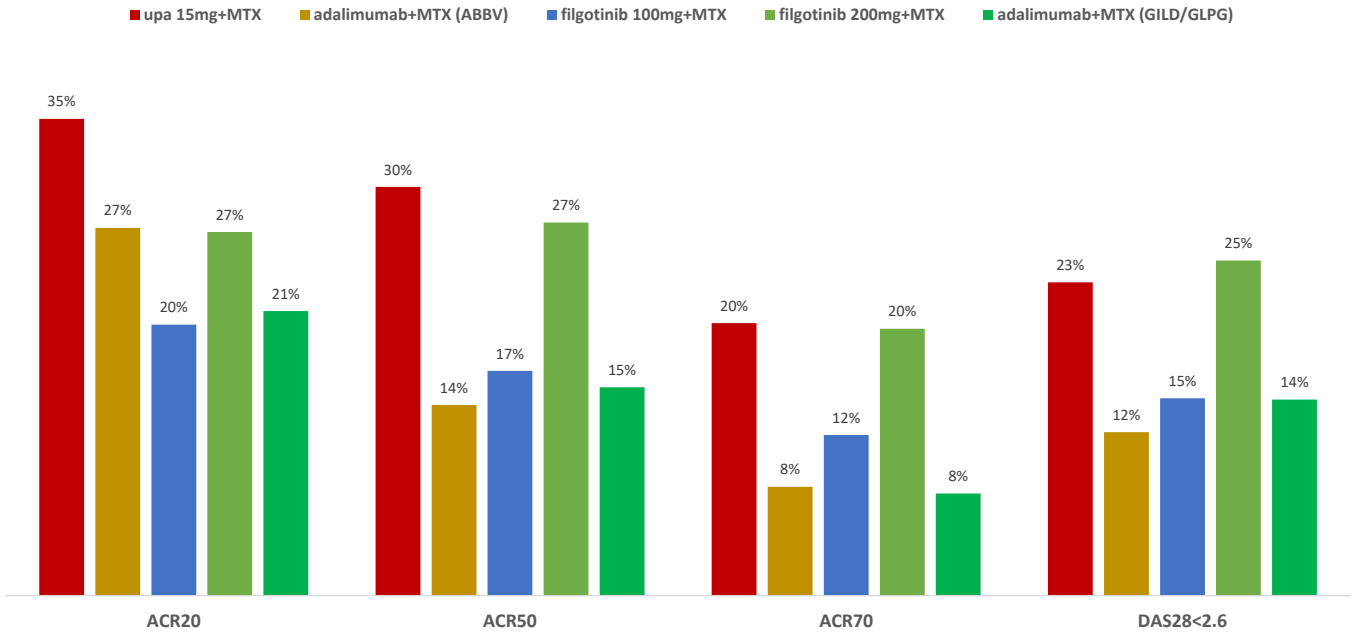


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Exhibit 3: FINCH 1 and SELECT-COMPARE efficacy data (Humira-adjusted; 12 weeks)

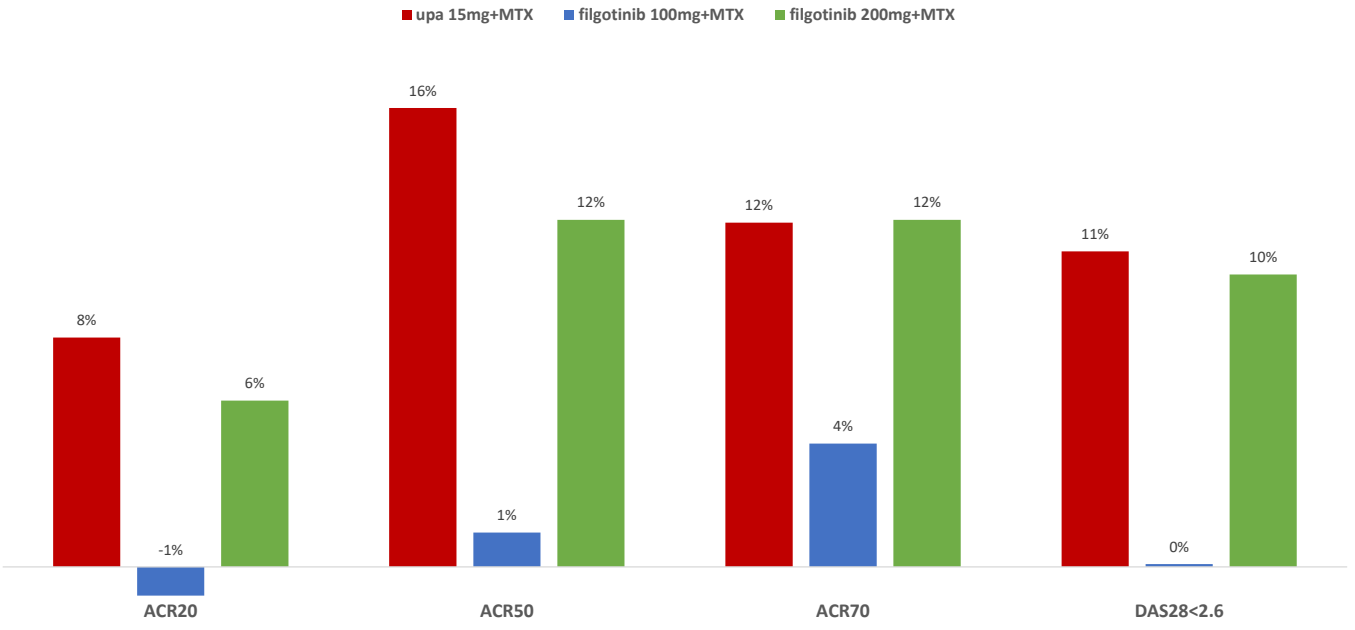

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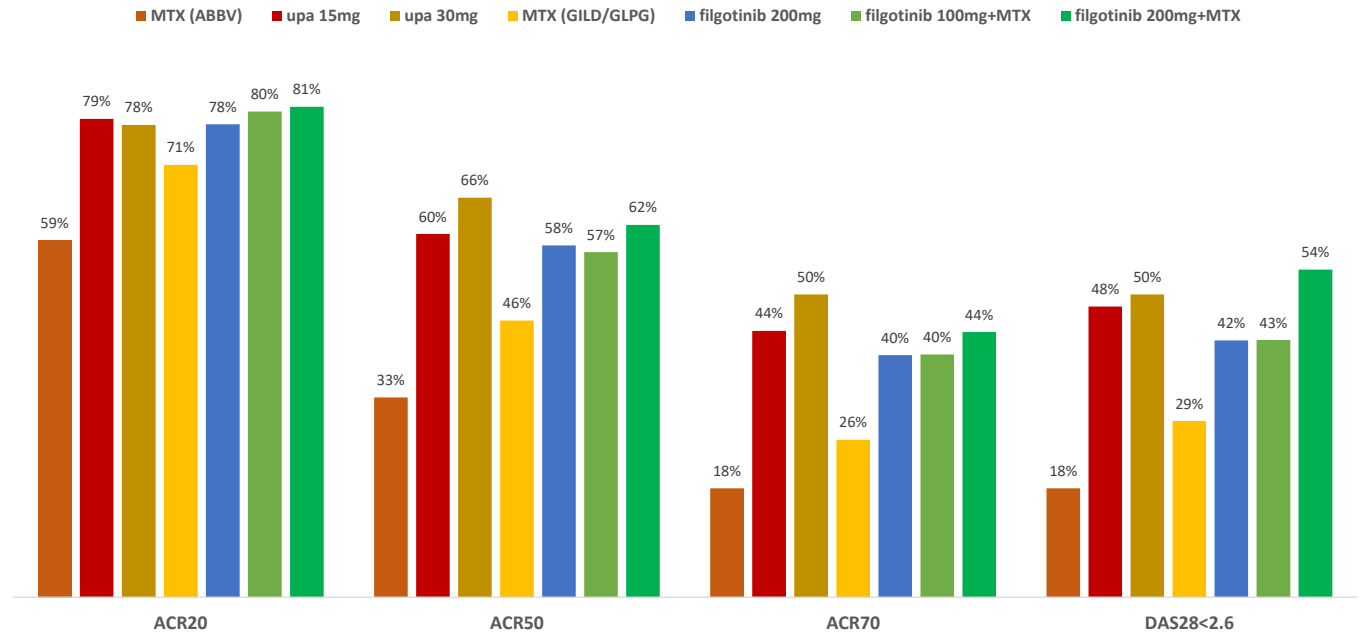
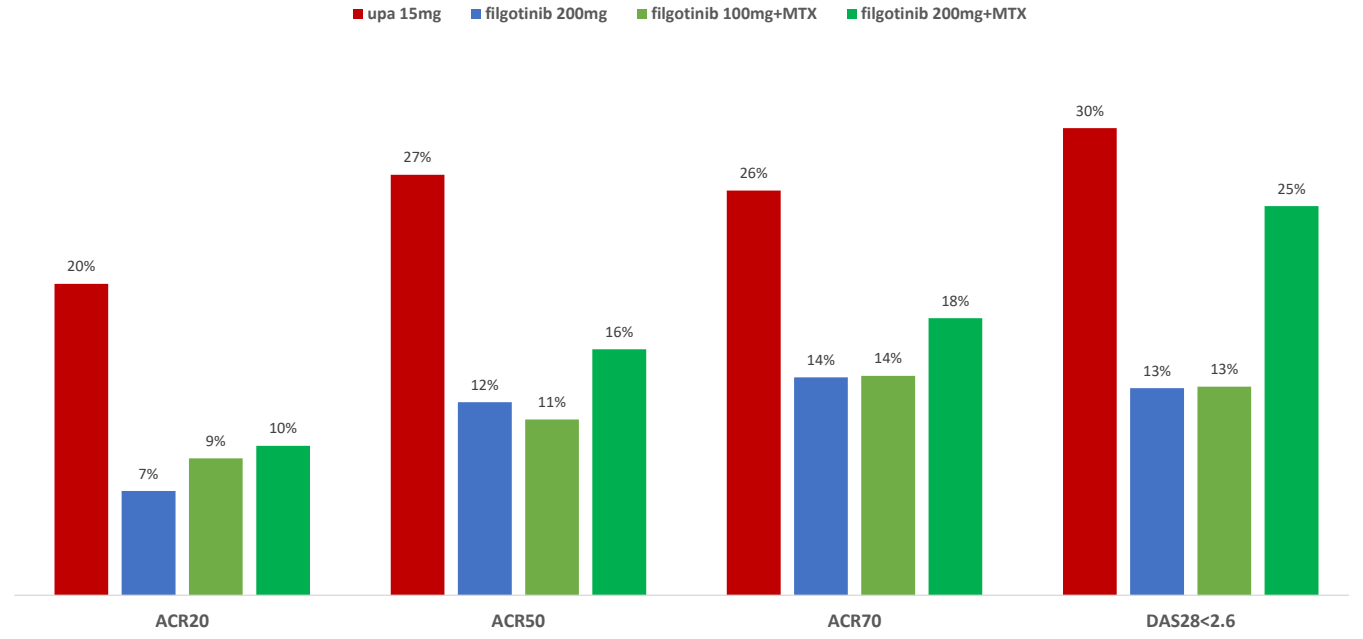
Exhibit 4: FINCH 3 and SELECT-EARLY efficacy data (unadjusted; 24 weeks)



Source: Company reports

Exhibit 5: FINCH 3 and SELECT-EARLY efficacy data (MTX-adjusted; 24 weeks)



Source: Company reports

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Companies mentioned

Galapagos NV (NASDAQ: GLPG US; $96.13; Sector Perform)
Gilead Sciences, Inc. (NASDAQ: GILD US; $63.69; Outperform)

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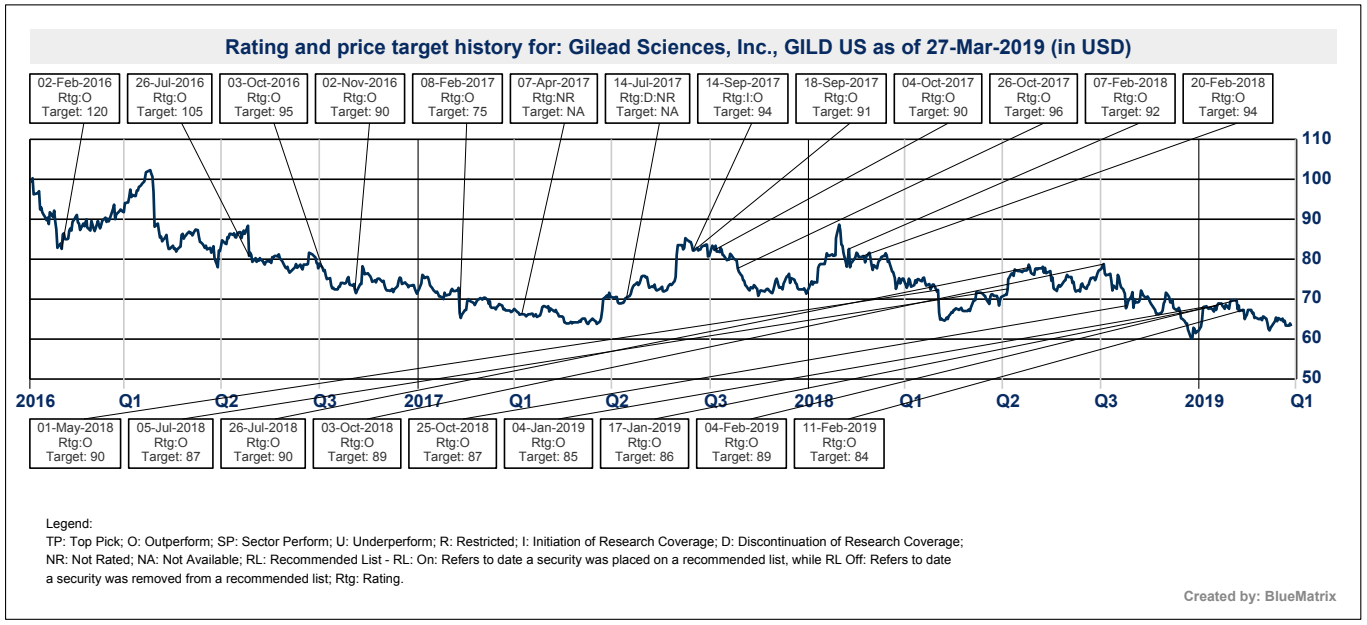

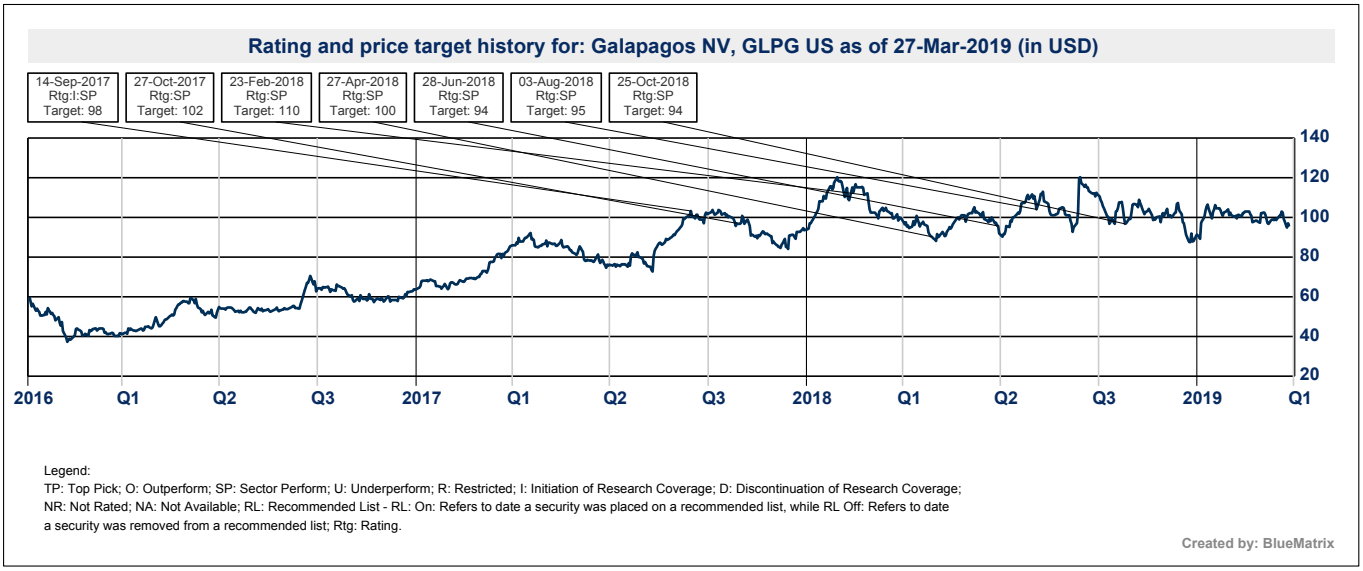

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Galapagos NV

Valuation

Our $94 price target blends DCF (using 11% discount rate and 2% terminal growth rate) and probability-adjusted multiples (30x on 2026E adjusted EPS discounted at 11%) analyses. This valuation supports our Sector Perform rating.

Risks to rating and price target

Risks include emergence of a safety issue, high regulatory bar for RA drugs like filgotinib, and limitations to interpreting early-stage data for '1690.

Gilead Sciences, Inc.

Valuation

Our $84 price target is derived via DCF analysis, with a 9% discount rate and a 3% terminal growth rate off 2027E (post-TAF generic). Our price target supports our Outperform rating.

Risks to rating and price target

Risks 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.

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