Some Welcome (+) Filgotinib Data - Safety Looks Quite Good

March 28, 2019

Key Takeaway

GILD reported positive data for its remaining two Phase III filgotinib studies in rheumatoid arthritis (FINCH-1 and -3). Each study was 3-4x the size of the first (FINCH-2) and efficacy/safety still looked clean/comparable to competitor data (e.g. ABBV, LLY), supporting our view that filgotinib may have the potential for multi-billion-dollar peak sales over time.

Efficacy for both studies look in line with competitors while safety continues to look clean. **Contact us for our detailed JAK side-by-side comparison spreadsheet**

Our take: (1) Overall data looks to be in line with the reported efficacy ranges of JAKs, **(2)** new pooled safety suggests filgotinib looks particularly good on the key concern of DVT/PE, showing essentially a 0.0-0.1% rate (lower than 0.3% for placebo and DMARDs). Deaths look balanced, malignancies lower, and cardiovascular MACE events similar, if not lower. These trends are generally seen in each individual study.

GILD acknowledges filing timelines are murky but the partners now plan to meet with regulators in Europe, Japan and US.

The totality of data continues to de-risk and solidify filgotinib as potentially best-in-class (e.g. especially on safety), which can serve as a helpful growth driver for GILD. We acknowledge that a key overhang is the ongoing male toxicity study (MANTA), but it could have interim data in Q3:19 and lead to a faster-than-expected filing shortly thereafter (e.g. file on interim rather than trial completion in 2020). Filings are pending post discussions with FDA.

Also, although filgotinib will likely be 4th to market after ABBV's JAK1 upadacitinib (filed Dec 20th, PDUFA in Q3:19), ABBV has higher instances of DVT/PEs and infections (per GLPG) while the other two competing JAKs already have black box warnings for serious infections, malignancy and/or thrombosis - yet consensus models peak sales of $3.5B + for PFE's Xeljanz, $1.5B+ for LLY's Olumiant, and $3.0B+ for ABBV. Moreover, (1) LLY baricitnib was approved only for the lower 2mg dose while (2) the FDA/EMA have issued safety alerts to PFE for increased risk of PE and deaths (based on interim data from an ongoing RA study).

Summary of efficacy results:

For FINCH-1 in 1,755 methotrexate-inadequate responders (MTX-IR): (1) wk-12 primary endpoint of ACR20 shows a placebo-adjusted benefit of 27% for high dose of 200mg filgotinib+MTX combo, which is comparable to 30-40% for competitors. **(2)** In addition, the high dose shows wk-12 efficacy of: 27% on ACR50 (vs 30-35% for competitors), 20% on ACR70 (vs 15-20%), 26% on low disease activity or DAS28-CRP<3.2 (vs 30-35%), and 25% on remission or DAS28-CRP<2.6 (vs 20-30%). **(3)** high dose filgotinib generally shows 0-10% more efficacy than the low dose, pointing to a clean dose response. **(4)** across endpoints, low dose looks similar to Humira while high dose is noticeably numerically better.

For FINCH-3 in 1,249 MTX-naive patients: (1) wk-24 primary endpoint of ACR20 shows a pbo-adjusted benefit of 10% for high dose of 200mg filgotinib monotherapy, in line with

FLASH NOTE	
RATING	BUY
TICKER	GILD
PRICE	$63.66^
PRICE TARGET (PT)	$95.00
MARKET CAP	$82.7B

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

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15-25% for competitors. **(2)** high dose also shows wk-24 efficacy of 16% on ACR50 (vs 15-30% for competitors), 18% on ACR70 (vs 20-30%) and 25% on remission (vs 15-30%). **(3)** again, high dose filgotinib generally shows 0-10% more efficacy than the low dose (clean dose response).

Company Description

Gilead Sciences

Gilead is a leader in the development and marketing of anti-infective drugs, with approved products for the treatment of HIV/AIDS, Hep C, hepatitis B, liver and pulmonology diseases. Gilead is developing a pipeline of antivirals, liver disease, immunology and oncology. The company has an extensive worldwide sales and marketing infrastructure.

Company Valuation/Risks

Gilead Sciences

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)

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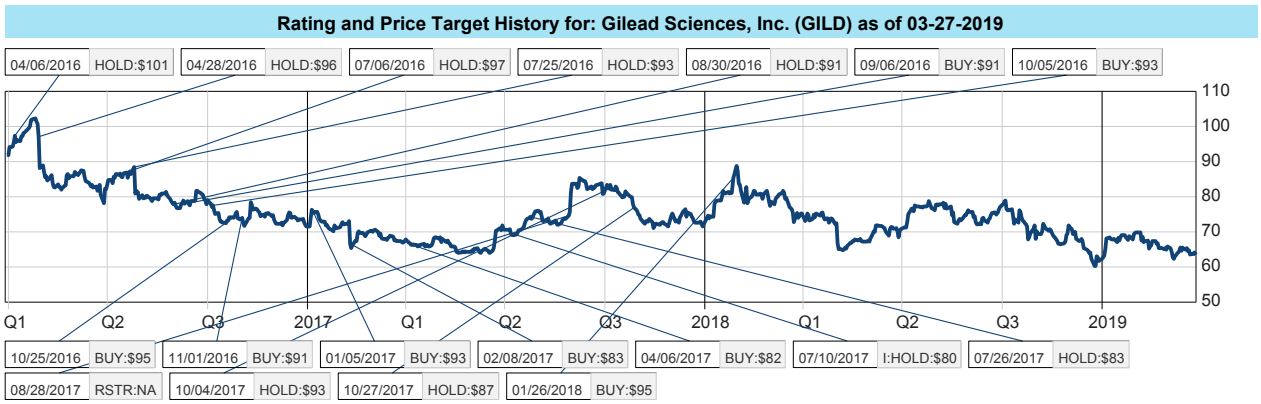
Other Companies Mentioned in This Report

- Gilead Sciences, Inc. (GILD: $63.66, BUY)



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Legend:

I: Initiating Coverage

D: Dropped Coverage

B: Buy

H: Hold

UP: Underperform

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Distribution of Ratings						
			IB Serv./Past12 Mos.		JIL Mkt Serv./Past12 Mos.	
	Count	Percent	Count	Percent	Count	Percent
BUY	1144	54.97%	96	8.39%	14	1.22%
HOLD	798	38.35%	10	1.25%	1	0.13%
UNDERPERFORM	139	6.68%	1	0.72%	0	0.00%

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