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After FDA rejection of a key drug, is Gilead still a turnaround story?

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Reprints[5]

Yichuan Cao/Sipa USA

The surprise decision[6] by the FDA to reject a Gilead Sciences (GILD[7]) drug for treating inflammatory diseases is clearly a setback for the biotech. The question now, though, is whether Gilead can still be considered a turnaround story that can diversify beyond its core virology business and return to growth levels seen in the past.

First, let's recap the news: The agency issued a complete response letter for filgotinib, a JAK inhibitor drug to treat rheumatoid arthritis, but wants more data on the effect on patient sperm counts. In particular, the FDA is concerned about toxicity for a 200mg dose. Gilead is running two studies to answer those concerns, but results are not going to be available until the first half of next year.

Although some analysts had suggested dosing was a risk factor, Gilead management had consistently expressed confidence in approval. Wall Street projected $2 billion in peak annual sales. For this reason, the drug became something of a litmus test for chief executive officer Daniel O'Day, who arrived early last year from Roche and quickly overhauled the leadership and began pursuing deals, mostly in oncology.

The immediate issue now becomes whether Gilead can compete against three other players that already sell JAK inhibitors. These belong to a family of medicines called DMARDs, or disease-modifying anti-rheumatic drugs, that combat autoimmune disorders, although a relatively recent entrant from AbbVie (ABBV[8]) is thought to be a primary rival.

More significant, though, is whether this scotches a long-term opportunity to expand more broadly into autoimmune diseases and beyond its HIV powerhouse franchise. Here is what the wags are saying:

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“Potentially of greater importance is what this (episode) may mean for management credibility,” wrote Tim Anderson of Wolfe Research to investors. “The bull case with Gilead has centered on it being a comparatively cheap, turnaround story with new management at the helm to take the company in new directions. In this context, a delay with a closely watched pipeline drug is a black eye.”

“The delay also helps cement the bear case which is that, outside of Gilead’s singular core area of expertise in virology, its R&D programs are quite possibly higher risk. While the company has several later-stage ‘shots on goal’ within its pipeline, almost all of these in fact are outside of virology.”

With an FDA approval for filgotinib this year, Gilead could have had a “fair chance” at competing for market share with AbbVie, which has a “formidable rheumatology sales force” centered around Humira, a blockbuster drug used to treat rheumatoid arthritis, Baird analyst Brian Skorney wrote to investors. But that may be tough now, with what looks like a year and a half delay. By then, AbbVie may be entrenched. Older JAK inhibitors, by the way, are sold by Pfizer (PFE[11]) and Eli Lilly (LLY[12]).

Even if a 100mg dose is approved, there is an increased risk that filgonotib will not be a competitive product, according to RBC Capital Markets analyst Brian Abrahams. Consequently, he wrote to investors, “this as a disappointment for Gilead in its mission to diversify into inflammation.”

Despite the setback, Gilead is “still a turnaround” story, Jefferies analyst Michael Yee wrote in his own investor note.

How so? In his view, O’Day has executed the HIV strategy, including long-acting drugs that are on the horizon. Gilead recently spent nearly $5 billion to buy Forty Seven[15], a cancer drug developer, and also made four other early-stage oncology partnerships and deals. Moreover, Gilead may reap up to $3 billion in sales this year for remdesivir, its experimental Covid-19 treatment.

That said, Yee readily acknowledges that Gilead “could use as many growth drivers as possible,” and noted there is what he called “reasonable debate” about whether the company should back off further filgotinib investment and put the money elsewhere.

About the Author Reprints[5]

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