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An expected blockbuster drug from Gilead is rejected, imperiling the biotech's future growth

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Yichuan Cao/Sipa USA via AP Images

Back before remdesivir became a household name, Gilead Sciences' most-discussed drug was filgotinib, a treatment for inflammatory disease expected to deliver billions of dollars in new revenue at a time when the biotech desperately needs it. All that got put in jeopardy on Tuesday night.

The FDA rejected Gilead's application to sell filgotinib as a treatment for rheumatoid arthritis and said it wouldn't reconsider until the company can provide more data on the drug's effect on patients' sperm counts. Gilead is

running two studies to determine exactly that, but it won't have results until sometime next year.

Gilead shares are down 6% to $65 in Monday premarket trading, a loss of nearly $6 billion in market value. Shares of Belgian drug maker Galapagos, which is in line to receive royalties on filgotinib sales, are down 29% to $133.

The surprise rejection imperils Gilead's long-term goal of building filgotinib into a major medicine. The plan was to start with rheumatoid arthritis and follow it with approvals in two types of inflammatory bowel disease, psoriatic arthritis, ankylosing spondylitis, and eye inflammation. Until the FDA signs off on the drug's safety, all of that is up in the air.

According to Gilead, the FDA also raised concerns about the "overall benefit/risk profile" of filgotinib when administered at a 200 mg dose, the highest offered to patients. If FDA limits filgotinib's approval to a lower dose only, the drug would be less effective compared to currently marketed oral medicines for rheumatoid arthritis, most notably Abbvie's Rinvoq, which was approved last year.

Without the 200 mg dose, Gilead may also be precluded from expanding filgotinib's use into other inflammatory diseases. In a recent study involving patients with ulcerative colitis, the response to filgotinib at a lower 100 mg dose failed to reach statistical significance.

Filgotinib and Rinvoq belong to a class of drugs called JAK inhibitors, which work by muting the activity of janus kinase enzymes — chemicals that help with immune response and cellular growth. Two other JAK inhibitors, Xeljanz from Pfizer and Olumiant from Eli Lilly, are also on the market as rheumatoid arthritis treatments.

In a research note commenting on Gilead's setback, RBC analyst Brian

Abrahams said, “Based on what we know about the FDA’s concerns, we see meaningful risk to future approvability in rheumatoid arthritis at the more competitive dose, as well as to future large inflammatory bowel disease indications; at the very least, we see a 6-12 month delay giving key competitors a greater head start.”

“If filgotinib label isn’t competitive, we believe Gilead won’t launch,” wrote Truist Securities analyst Robin Karnauskas, after speaking with Gilead management on Tuesday night.

Gilead took a calculated risk by seeking U.S. approval for filgotinib without safety data clearing the drug’s effect on sperm count — a safety signal seen in certain animal studies. Now, the company has to wait for those safety data to read out from two clinical trials expected to complete in the first half of next year.

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