

Lilly's rheumatoid arthritis pill rejected by regulators

April 14 2017, by Linda A. Johnson



This Thursday, June 30, 2011, file photo shows a sign in front of the Eli Lilly and Company corporate headquarters in Indianapolis. On Friday, April 14, 2017, Eli Lilly said U.S. regulators have rejected its much-anticipated pill for the immune disorder rheumatoid arthritis, the drugmaker's second drug development setback since November 2016. (AP Photo/Darron Cummings, File)

Eli Lilly said U.S. regulators have rejected its much-anticipated pill for the immune disorder rheumatoid arthritis, the drugmaker's second drug

development setback since November.

The Food and Drug Administration said in a letter to the company that it needed more information about the drug's safety and the best doses, Lilly said Friday in a statement.

Lilly said it disagrees with FDA's conclusions but will work with the agency on a plan to eventually get the drug, baracitinib, approved for U.S. patients.

In November, Lilly's experimental medicine solanezumab flopped in a closely watched test in patients with mild Alzheimer's disease, after having already failed in testing in patients with more advanced Alzheimer's.

The arthritis drug, which has the proposed brand name Olumiant and was approved for use in Europe in February, was expected to be a big seller in part because most other new rheumatoid arthritis drugs are injected, making them less appealing for patients.

Christi Shaw, president of the Lilly division that developed the drug, said the company remains confident in the drug's ability to safely treat moderate and severe rheumatoid arthritis.

About 23 million people worldwide, three-fourths of them women, have rheumatoid arthritis, a chronic disorder in which the immune system attacks the body's tissues. It causes painful swelling and progressive destruction of joints, which can leave them deformed and, in severe cases, lead to disability. It can also damage other body parts, including the skin, eyes, lungs, heart and blood vessels.

Eli Lilly & Co. and Incyte Corp., its partner in developing baracitinib, applied for FDA approval of the drug in January 2016. Normally the

review process takes 10 months, but this January, FDA said it needed three additional months to review more information. Still, drug industry analysts as recently as this week were advising clients that approval of baracitinib was likely.

Despite the setback, Lilly reaffirmed its 2017 financial forecasts Friday, for earnings per share of \$2.69 to \$2.79, excluding one-time items, and revenue between \$21.8 billion and \$22.3 billion. It said Incyte, which is based in Wilmington, Delaware, was evaluating the rejection's impact on its position and would update investors when it reports first-quarter results, likely in mid-May. Lilly is expected to report its quarterly results on April 25.

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