Pfizer says patient died in oral RA drug study

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(AP) -- Pfizer Inc. confirmed that one patient who was taking its drug candidate tofacitinib, a pill designed to treat rheumatoid arthritis, died during a recent clinical trial and said the death was connected to the drug.

The world's largest drugmaker said the patient died of respiratory failure. Three other patients who were treated with tofacitinib during the study died as well, but those deaths were not determined to be drug-related. Two of those deaths occurred several weeks after the patients stopped taking tofacitinib. Tofacitinib, formerly called tasocitinib, is being tested as a treatment for moderate to severe rheumatoid arthritis, a chronic autoimmune disease that causes inflammation, usually of the hands and feet.

More than 1,000 patients have taken tofacitinib during clinical trials, and Pfizer said late Thursday that overall death rate for patients in those studies is similar to what has been observed in other biologic treatments for rheumatoid arthritis.

The late-stage trial was called ORAL Sync. Pfizer said in March that tofacitinib met its main goals in the 792-patient study. The patients received either 5 or 10 milligrams of the drug twice per day. Some patients received a placebo. The trials involved patients with moderate to severe active rheumatoid arthritis who have not been helped by an older class of drugs including methotrexate. Pfizer will present full results from the ORAL Sync trial on May 27 at a conference of the European

League Against Rheumatism.

Earlier this month Pfizer said the drug met its goals in a separate late-stage trial.

Pfizer said the other deaths included a patient who died of acute heart failure, one death caused by brain injury following trauma, and one case of worsening rheumatoid arthritis. The brain injury death occurred 22 days after the patient stopped taking tofacitinib, and the patient who died of worsening rheumatoid arthritis had stopped taking tofacitinib six weeks earlier.

Analysts downplayed the report, saying the deaths are not unusual in studies of rheumatoid arthritis drugs. Credit Suisse analyst Catherine Arnold said the death rates in studies of tofacitinib are similar to approved therapies like Humira and Simponi, made by Abbott Laboratories and Johnson & Johnson, respectively. Arnold said that, according to Pfizer, there is some evidence the patient whose death was connected to tofacitinib had pre-existing lung disease. However the patient did not have a diagnosed lung disease.

Citi Investment Research analyst John Boris said investors were more likely to focus on the patient who died of acute heart failure. He said rheumatoid arthritis drugs like Humira, Simponi and Enbrel are restricted in patients with a heart failure because rheumatoid arthritis is linked to the disease and because there is evidence that those drugs can worsen congestive heart failure.

Boris said it's possible that drugs like tofacitinib have a similar effect. He still expects the drug will eventually be approved and reach $800 million in annual sales.

Humira, Simponi and Enbrel are all injectable drugs that work by

suppressing an immune system cell called TNF-alpha, or tumor necrosis factor alpha. Tofacitinib blocks janus kinases, a type of enzyme that is involved in inflammatory diseases and other illnesses.

The most common side effects of treatment with the drug have included bronchitis, headache, infections, and gastrointestinal symptoms like nausea, vomiting, and diarrhea. More serious side effects in a mid-stage trial included lower levels of a type of white blood cell called neutrophils, higher cholesterol levels, and increased creatinine levels.