FDA: Pulmonary embolism risk up with tofacitinib 10 mg for RA

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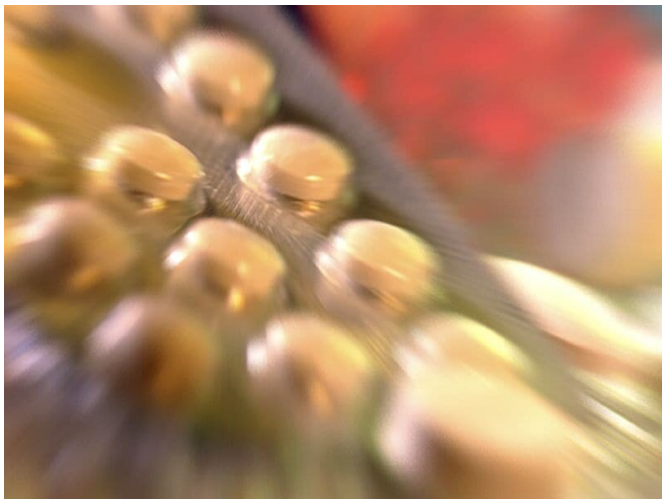

(HealthDay)—A safety clinical trial has revealed that tofacitinib (Xeljanz, Xeljanz XR) 10 mg twice daily is associated with an increased risk for pulmonary embolism (PE) and death among patients with rheumatoid arthritis (RA), the U.S. Food and Drug Administration warned in a safety alert this week.

Currently, the 10-mg dose of tofacitinib is only approved in the dosing regimen for patients with ulcerative colitis. When tofacitinib received FDA approval, the agency called for a clinical trial among RA patients to evaluate the risk for heart-related events, cancer, and infections with tofacitinib doses of 5 mg and 10 mg twice daily combined with methotrexate compared to a tumor necrosis factor inhibitor. Patients enrolled in the clinical trial were ?50 years old and had one or more cardiovascular risk factors.

In its most recent analysis of the clinical trial, an external data safety monitoring committee found an increased risk for PE and death in the patients treated with tofacitinib 10 mg twice daily compared with those who received tofacitinib 5 mg twice daily or a TNF inhibitor. The FDA recommends that health care professionals follow tofacitinib prescribing information for the specific condition they are treating and that they monitor patients for signs and symptoms of PE.

Pfizer is now transitioning trial patients taking the 10-mg dose to the 5-mg dose. "This trial will continue and is expected to be completed by the end of 2019. We are working with the manufacturer to evaluate other currently available safety information for tofacitinib and will update the public with any new information based on our ongoing review," the FDA wrote in a safety announcement.

More information: More Information