US approves Sanofi, Regeneron arthritis drug

May 23 2017

US federal regulators have given the green light to French pharmaceutical company Sanofi and its US partner Regeneron to market a drug to treat the chronic inflammatory condition, rheumatoid arthritis.

The Food and Drug Administration authorisation had been delayed over "deficiencies" found by the regulatory agency during an inspection of the Sanofi manufacturing site in the Normandy region of France.

The drug sarilumab—which will be marketed under the brand name Kevzara—could generate $1.8 billion in sales by 2020, and is considered by Sanofi as a future flagship product to support long-term growth.

Canadian regulators made a similar ruling in February. The European Medicines Agency gave the drug a favorable opinion in April, according to Sanofi, prior to a final European Commission decision expected in the coming months.

In Europe, some 2.9 million people suffer from rheumatoid arthritis, a painful autoimmune disorder that causes joint pain, swelling, stiffness and fatigue.

Treatments that already exist for the condition include the anti-inflammatory Humira, from the US company AbbVie, as well as biosimilars—products that mimic the effects of more costly biologic drugs made from living cells.