

Sandoz buys Pfizer's biosimilar infliximab

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Sandoz, a Novartis company and a global leader in biosimilars, has acquired from Pfizer the rights for the development and commercialization of PF-06438179 (biosimilar infliximab) in the 28 countries that form the European Economic Area (EEA). Infliximab is a tumor necrosis factor alpha (TNF- α) inhibitor used to treat a range of autoimmune diseases including rheumatoid arthritis (RA) and psoriasis.

"Infliximab is one of the most important biologic therapy options for people living with severe autoimmune diseases such as rheumatoid arthritis" said Mr Richard Francis, division head and CEO Sandoz. "We intend to complete the development and registration of PF-06438179 and make it available to patients across Europe as part of our robust portfolio of immunology treatments."

Under the terms of the deal, Sandoz plans to complete the clinical study program and submit the biosimilar infliximab to the European Medicines Agency (EMA) for regulatory approval and registration with the European Commission. Included in the program is a global phase III trial - REFLECTIONS (B537-02) investigating the safety and efficacy of PF-06438179 and infliximab in combination with methotrexate in subjects with active rheumatoid arthritis who have had an inadequate response to methotrexate. Sandoz acquired the rights to infliximab, following Pfizer's commitments to the European Commission in connection with the acquisition of Hospira, to divest the program.

Sandoz plans to make 10 regulatory filings over a three year period (2015-2017) having already announced five, which include biosimilar etanercept filed with both the EMA and the US Food and Drug Administration.

