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ASIA EDITION

Sanofi and Regeneron announce approval of Kevzara to treat rheumatoid arthritis in the European Union

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Kevzara is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and blocks pro-inflammatory IL-6 mediated signaling

Sanofi and Regeneron Pharmaceuticals, Inc. recently announced today that the European Commission (EC) has granted marketing authorization for Kevzara® (sarilumab) in combination with methotrexate (MTX) for the treatment of moderately to severely active rheumatoid arthritis (RA) in adult patients who have responded inadequately to or who are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs)

Kevzara is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and blocks pro-inflammatory IL-6 mediated signaling. Elevated levels of IL-6 are found in the synovial fluid of patients with RA and play an important role in both the pathologic inflammation and joint destruction which are hallmarks of RA.1

Elias Zerhouni, M.D., President, Global R&D, Sanofi said, “RA is a difficult-to-treat, lifelong disease and many healthcare providers are challenged with finding a treatment that works for their patients. Kevzara works differently than some of the other most commonly used biologics, and its approval is good news for the many patients with a high unmet need.”

George D. Yancopoulos, M.D., Ph.D., Founding Scientist, President, and Chief Scientific Officer, Regeneron said, “We are pleased to bring Kevzara to European patients who may not be responding to the most commonly used biologics such as TNF inhibitors, or who may be seeking an effective monotherapy to reach their treatment goals. This approval was made possible through the hard work of our innovative scientists, as well as thousands of dedicated investigators and patients around the world who participated in the SARIL-RA clinical trial program.”

The EC approval is based upon receipt of a positive opinion by European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), which evaluated results from seven Phase 3 trials in the global SARIL-RA clinical development program. These studies incorporate data from more than 3,300 adults with moderately to severely active RA who have had an inadequate response or intolerance to one or more biologic or non-biologic DMARDs.

The program includes the Phase 3 MONARCH study, in which treatment with Kevzara 200 mg monotherapy was superior to adalimumab 40 mg (marketed by AbbVie as HUMIRA®) monotherapy in reducing disease activity and improving physical function, with more patients achieving clinical remission over 24 weeks.

The recommended dose of Kevzara is 200 mg once every 2 weeks administered as a subcutaneous injection with a prefilled syringe or prefilled pen. Reduction of dose from 200 mg once every 2 weeks to 150 mg once every 2 weeks is recommended to help manage certain laboratory abnormalities (neutropenia, thrombocytopenia, and liver enzyme elevations).

The most frequent adverse reactions observed with Kevzara in clinical studies were neutropenia, increased alanine aminotransferase, injection site erythema, upper respiratory infections, and urinary tract infections. The most common serious adverse reactions were infections.