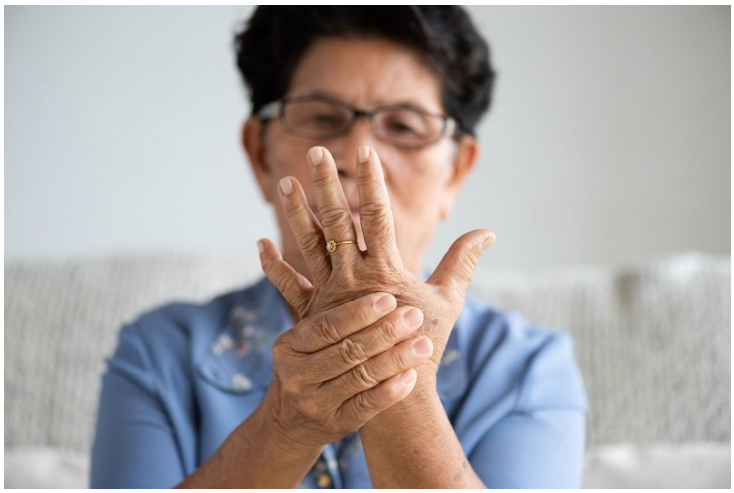
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Japan approves subcutaneous injection formulation for rheumatoid arthritis

28 September 2022 | News

Metoject will be the first self-administrable MTX subcutaneous injection formulation for rheumatoid arthritis inJapan



Eisai and nippon medac Co. have obtained manufacturing and marketing approval from the Japanese Ministry of Health, Labour and Welfare for the indication of the anti-rheumatic agent "Metoject Subcutaneous Injection 7.5mg syringe 0.15mL, 10mg syringe 0.20mL, 12.5mg syringe 0.25mL and 15mg syringe 0.30mL" (methotrexate, MTX) for the treatment of rheumatoid arthritis.

Metoject will be the first self-administrable MTX subcutaneous injection formulation for rheumatoid arthritis in Japan. Based on the license agreement signed by Eisai and medac GmbH in May 2019, nippon medac will hold the marketing authorization of Metoject, while Eisai will be responsible for product distribution of Metoject in Japan.

The approval is based on the results of a Phase III clinical trial (MC-MTX.17/RA) conducted in Japan by nippon medac to compare the efficacy and safety of Metoject with that of oral MTX, which consisted of a double-blind phase and an extension phase.

It is reported that there are approximately 700,000 - 800,000 rheumatoid arthritis patients in Japan. MTX is used as the first-line option for the treatment of rheumatic arthritis, but only the oral formulation is available in Japan. Eisai and nippon medac will provide a self-administrable subcutaneous injection as a new treatment option for rheumatoid arthritis patients in Japan as soon as possible, and will make further contributions to address the diversified needs of, and increase the benefits provided to, rheumatoid arthritis patients.