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Eisai Co., Ltd.
nippon medac Co., Ltd.

METOJECT® SUBCUTANEOUS INJECTION PEN (METHOTREXATE) PEN-TYPE AUTOINJECTOR APPROVED IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and nippon medac Co., Ltd. (Headquarters: Tokyo, CEO: Hirohisa Iriyama, “nippon medac”), a subsidiary of medac Gesellschaft für klinische Spezialpräparate mbH (Headquarters: Germany, “medac GmbH”) announced today that they have obtained manufacturing and marketing approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the additional formulation of Metoject Subcutaneous Injection for the anti-rheumatic agent, pen-type autoinjector “Metoject® Subcutaneous Injection 7.5mg Pen 0.15mL, 10mg Pen 0.20mL, 12.5mg Pen 0.25mL and 15mg Pen 0.30mL” (methotrexate). 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.

This formulation incorporates the previously MHLW-approved Metoject Subcutaneous Injection pre-filled syringe formulation in a pen-type autoinjector and was developed to reduce the burden on patients and improve safety during self-injection. The drug can be self-injected in two steps (1- removing the cap, 2- pressing the pen against the skin). The built-in needle cover prevents the needle from being seen prior to administration and automatically locks after administration to prevent accidental skin puncture.

It is estimated that there are approximately 700,000 - 800,000 rheumatoid arthritis patients in Japan,¹ and methotrexate is used as the first-line option for the treatment of rheumatic arthritis. Eisai and nippon medac are committed to delivering this treatment option to reduce the burden on patients with rheumatoid arthritis, and will make further contributions to address the diversified needs of, and increase the benefits provided to, rheumatoid arthritis patients.

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[Notes to editors]

1. About Metoject® Subcutaneous Injection Pen (methotrexate)

Methotrexate (MTX) is positioned as the anchor drug for rheumatoid arthritis treatment.² For rheumatoid arthritis, it is believed that MTX regulates cell growth by inhibiting folate metabolism in lymphocytes and other cells, and also has an anti-inflammatory mechanism through the promotion of adenosine synthesis in vascular endothelial cells and other cells in synovial membranes. Metoject Subcutaneous Injection Pen will be the first self-administrable MTX subcutaneous injection pen-type autoinjector for rheumatoid arthritis in Japan. It is approved in more than 16 countries in Europe.

2. About Eisai

Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept (also known as our *human health care (hhc)* Concept), we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, our continued commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), is demonstrated by our work on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), and connect with us on [X](#), [LinkedIn](#) and [Facebook](#).

3. About nippon medac

nippon medac Co., Ltd. was established in April 2016 as the Japanese subsidiary of medac GmbH. We are working to develop new drugs that can expand treatment options for diseases for which therapeutic requirements have not yet been fully met. We will work diligently to deliver quality drugs as quickly as possible to improve the quality of life of patients and their families in areas with high medical need.

¹ Report from Study Committee on Rheumatoid Arthritis and Allergy

<http://www.mhlw.go.jp/stf/houdou/2r9852000001nfao-att/2r9852000001nfdx.pdf>

² Japan College of Rheumatology, Clinical practice guideline of methotrexate for patients with rheumatoid arthritis: 2016 updated version