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Eisai Co., Ltd.

EISAI ANNOUNCES LAUNCH OF ANTI-RHEUMATIC AGENT CARERAM®

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will launch the anti-rheumatic agent Careram® (iguratimod) in Japan on September 12 for the treatment of rheumatoid arthritis. Careram, jointly developed in Japan by Eisai and Toyama Chemical Co., Ltd. from the Phase III clinical development stage, was approved by Japan's Ministry of Health, Labour and Welfare (MHLW) in June of this year and was subsequently listed on the National Health Insurance Drug Price List on August 28.

Careram is a novel disease-modifying anti-rheumatic drug (DMARD) that exhibits anti-rheumatic effects by primarily suppressing the production of immunoglobulin and inflammatory cytokines. In a Phase III clinical study of Careram administered as a monotherapy in patients with rheumatoid arthritis, Careram demonstrated superiority over placebo as well as non-inferiority compared to an existing DMARD (salazosulfapyridine). It is also the only oral anti-rheumatic agent currently approved in Japan to demonstrate efficacy in domestic clinical trials as an add-on therapy to methotrexate ("MTX"), the standard of care, in rheumatoid arthritis patients who did not achieve satisfactory benefit with MTX alone. In a trial of Careram in combination with MTX¹⁾ conducted in this patient population, patients who were administered a combination of the two agents demonstrated favorable tolerability as well as significant improvements compared to those treated with placebo (MTX-only arm) in the study's primary endpoint of ACR20 response rate at Week 24.

In Japan, rheumatoid arthritis is said to affect an estimated 700,000 to 800,000 patients. Eisai, which currently markets the rheumatoid arthritis treatment Humira®²⁾ and the analgesic/anti-inflammatory agent Infree®, has extensive data and experience in the field of rheumatoid arthritis. By providing Careram as a new option for the pharmacological treatment of rheumatoid arthritis, Eisai believes that it can make further contributions to address the diversified needs of rheumatoid arthritis patients and increase their quality of life. Eisai will conduct a post-marketing special use results survey (all-case surveillance) in all patients who are administered Careram until a pre-determined number of patients has been reached in accordance with an approval condition imposed by the MHLW. After confirming the safety of Careram through the all case surveillance, Eisai will strive to provide information on proper use of the agent in hope that more patients will use it.

¹⁾ Notes to editors: "2. About the Careram-MTX Combination Trial"

²⁾ Co-promoted with Abbott Japan Co., Ltd. under a one brand, one channel, two promotion scheme.

[Please refer to the following notes for a product outline, further information on the Careram-MTX combination trial, a glossary of terms, an overview of Eisai's Commitment to the Field of Rheumatoid Arthritis and a product photograph]

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[Notes to editors]

1. Product Outline

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| 1) Product Name: | Careram® Tablets 25 mg | |
| 2) Generic Name: | iguratimod | |
| 3) Indications and Usage: | Rheumatoid arthritis | |
| 4) Dosage and Administration: | The recommended adult dosage of iguratimod is one 25 mg tablet taken orally once daily after breakfast for at least four weeks, after which the dosage should be increased to one 25 mg tablet taken twice daily (after breakfast and after dinner). | |
| 5) Listed price: | Careram® Tablets 25 mg | 150.50 yen per tablet |
| 6) Packaging: | Careram® Tablets 25 mg | 100 tablet (blister packaging) box |

2. About the Careram-MTX Combination Trial

The Careram-MTX combination trial was a 52 week trial conducted in rheumatoid arthritis patients who did not achieve satisfactory benefit with MTX alone. The trial was conducted in two phases: a double-blinded phase that evaluated the efficacy and safety of Careram in combination with MTX compared to MTX in combination with placebo; and a continuation period that evaluated the long-term safety of Careram-MTX in all patients. In the study's primary end point of ACR20 (see 5 for further details) response rate at Week 24, patients treated with Careram demonstrated a 69.5% (114/164 patients) improvement as compared to a 30.7% (27/88 patients) improvement amongst those patients administered placebo, with the Careram arm showing a significant improvement in ACR20 response rate over the placebo arm ($p < 0.001$). At Week 24, the rate of adverse drug reactions was 51.8% (85/164 patients) and 33.0% (29/88 patients) in the Careram and placebo arms, respectively, and 65.2% (107/164 patients) in the Careram arm at Week 52.

3. Rheumatoid Arthritis

Rheumatoid arthritis is a disease that leads to the inflammation of multiple joints throughout the body, causing joint swelling and pain. With joint destruction progressing right from the early stages of the disease, rheumatoid arthritis causes joint deformities and functional impairment over the long term. Rheumatoid arthritis is an autoimmune disease in which synovial cells, which line the inner surface of the joint cavity, proliferate due to an unknown cause. The number of blood vessels in joints also increases, resulting in the migration of lymphocytes, macrophages and other white blood cells from inside blood vessels to the synovial tissue of joints. An immune reaction in localized joints causes an inflammatory reaction and the progression of cartilage and bone destruction due to the effects of cytokines produced by lymphocytes and macrophages. In Japan, rheumatoid arthritis is said to affect an estimated 700,000 to 800,000 patients.

4. Disease Modifying Anti-Rheumatic Drug (DMARD)

DMARDs (Disease Modifying Anti-Rheumatic Drugs) are a category of drugs that work to control the underlying processes of rheumatoid arthritis. They are expected to control the immune abnormalities that are thought to cause inflammation in the disease.

5. ACR20 Response Rate

ACR20 is a criterion developed by the American College of Rheumatology that measures improvement in clinical symptoms of rheumatoid arthritis. It expresses the percentage of patients who demonstrated a 20% or greater

improvement in tender and swollen joint counts and at least three of the following five disease activity variables: patient assessment of pain; patient assessment of global disease activity; physician assessment of global disease activity; patient assessment of physical function; and chronic response protein (CRP) or erythrocyte sedimentation rate (ESR) concentrations.

6. Eisai's Commitment to the Field of Rheumatoid Arthritis

In Japan, Eisai currently markets the fully human anti-TNF- α monoclonal antibody Humira[®] (adalimumab) under a one brand, one channel, two promotion scheme with Abbott Japan Co., Ltd.. Humira, the world's first fully human anti-TNF α monoclonal antibody, exerts its effects by neutralizing TNF- α (tumor necrosis factor-alpha), a protein that plays a central role in inflammatory responses in diseases such as rheumatoid arthritis. Humira was approved for the additional indications of juvenile idiopathic arthritis (juvenile rheumatoid arthritis) and inhibition of structural damage of joints in patients with rheumatoid arthritis in July 2011 and August 2012, respectively. Eisai has also established the treatment support program, "myHUMIRA," for rheumatoid arthritis patients receiving treatment with Humira, through which it provides patients with information on the disease, treatment and issues pertaining to daily life. By providing the newly-launched Careram as a new option for the pharmacological treatment of rheumatoid arthritis, Eisai believes that it can make further contributions to address the diversified needs of rheumatoid arthritis patients and to increase their quality of life.

[Product Photograph]

