FOR IMMEDIATE RELEASE
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Abbott Japan Co., Ltd.
Eisai Co., Ltd.

Abbott Japan and Eisai Receive Approval to Market the Fully Human Anti-TNF-Alpha Monoclonal Antibody Humira® (adalimumab) For the Inhibition of Structural Damage of Joints in Patients with Rheumatoid Arthritis

Abbott Japan Co,. Ltd. (Headquarters: Tokyo, President: Gary M. Winer, "Abbott Japan") and Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that they have received approval from Japan's Ministry of Health, Labour and Welfare to market Humira® Pre-filled Syringe 40 mg/0.8 mL for Subcutaneous Injection (adalimumab [genetical recombination]), a fully human anti-TNF-alpha monoclonal antibody developed by the two companies in Japan, for the additional indication of inhibition of structural damage of joints in patients with rheumatoid arthritis (RA).

In principle, the use of Humira is limited to RA patients who have had an inadequate response to conventional therapy. However, the approval of this latest indication will enable the drug to be administered to patients with rapid progression of structural damage even if they have not received prior treatment with anti-rheumatic drugs. Humira is the first and only biologic agent in Japan to be approved for use in such patients, and is expected to contribute to the treatment of RA patients.

This approval of the new indication is based on favorable results from Study HOPEFUL 1, which evaluated Humira in combination with the first-line RA treatment methotrexate ("MTX") versus MTX monotherapy in RA patients who had received no prior treatment with MTX. The study demonstrated that combination treatment with Humira had a significantly greater inhibitory effect on the progression of joint destruction compared to MTX alone in the study's primary endpoint of modified Total Sharp Score (a measure of joint destruction).

"The goal of RA treatment is to improve a patient's long-term quality of life to the greatest extent possible through three key approaches－symptomatic control, inhibition of structural changes such as joint destruction, and normalization of physical function and participation to social activities. Preventing damage to joints or bones is the most important of these approaches as it plays a major factor in determining a patient's course of treatment. The approval of inhibition of structural damage of joints as an additional indication for Humira is extremely significant in that the drug has been proven to achieve one of these key treatment goals," said Dr. Tsutomu Takeuchi, Professor of Medicine, Division of Rheumatology, Department of Internal Medicine, School of Medicine, Keio University. "Furthermore, the approval is also welcome news that has important implications for early-stage RA patients who are experiencing rapid joint destruction in that Humira is the first treatment option to be approved in Japan for use based on treatment guidelines in RA patients with rapid progression of structural damage, including those who have not received prior treatment with anti-rheumatic drugs－a patient population in which Humira is already widely used in Europe and the United States. Going forward, I firmly believe that Humira will play an even greater role than ever before in helping us to achieve RA treatment goals."

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In Japan, Abbott Japan is the marketing and manufacturing authorization holder for Humira, while Eisai is responsible for its distribution. The two companies are working together to promote the product under a “one-brand, one-channel, two-promotion” scheme.

Abbott Japan and Eisai remain committed to ensuring, and providing information on, the proper use of Humira as they seek to make further contributions to improve the quality of life of RA patients.

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