

FOR IMMEDIATE RELEASE

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Abbott Japan Co., Ltd.
Eisai Co., Ltd.

Abbott Japan and Eisai have Cleared the Condition for Approval of Humira[®], a Fully Human Anti-TNF- α Monoclonal Antibody, for Plaque Psoriasis and Psoriasis Arthropica in Terms of the All-Case Surveillance

Abbott Japan Co., Ltd. (Pharmaceutical Products Group 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 notification from Japan's Ministry of Health, Labour and Welfare (MHLW) that the condition for approval of Humira[®] pre-filled syringe 40 mg/0.8 mL for subcutaneous injection (adalimumab [genetical recombination]), a fully human anti-TNF- α monoclonal antibody, has been lifted in terms of a drug use results survey (all-case surveillance) for plaque psoriasis and psoriasis arthropica.

In approving plaque psoriasis and psoriasis arthropica as additional indications for Humira in January 2010, the MHLW imposed the following condition: "A post-marketing drug use results survey of all patients receiving Humira must be conducted until data has been collected for a pre-determined number of cases in order to promptly obtain safety and efficacy data for the drug, and appropriate measures must be taken to ensure its proper use."

The MHLW lifted the condition for approval based on a review of safety and efficacy data for Humira submitted to the Ministry in an interim report outlining analysis results of the all-case surveillance of 634 patients with plaque psoriasis and psoriasis arthropica.

Based on evidence obtained through the survey, Abbott Japan and Eisai will continue to ensure, and provide information on, the proper use of Humira as they seek to make further contributions to improve the quality of life of patients.

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