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

Abbott Japan and Eisai Clear All-Case Surveillance Condition for Approval of Humira®, a Fully Human Anti-TNF-α Monoclonal Antibody, in the Treatment of Crohn's Disease

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 "all-case surveillance" drug use-results survey condition required for approval of the Humira® (adalimumab [genetical recombination]) pre-filled syringe 40 mg/0.8 mL for subcutaneous injection, a fully human anti-TNF-α monoclonal antibody, has been lifted, approving Humira's use in induction and maintenance of clinical remission in patients with moderately to severely active Crohn's disease (CD).

In October 2010, the MHLW approved moderately to severely active CD as an additional indication for Humira with the following condition for approval: "To promptly obtain safety and efficacy data on the drug and ensure that appropriate measures are taken to establish its proper use, a post-marketing drug use-results survey of all CD patients receiving Humira must be conducted until sufficient data can be collected for a predetermined number of cases."

The MHLW lifted this condition for approval based on a review of safety and efficacy data on Humira submitted to it in an interim report outlining analysis results of the all-case surveillance of 704 patients with moderately to severely active CD.

Clinical studies of Humira have been carried out extensively to date and a wide literature of clinical data exists on the drug. Today, Humira is administered to more than 600,000 patients worldwide. In Japan, Abbott Japan is the marketing and manufacturing authorization holder for Humira, while Eisai is responsible for distribution. The two companies are working together to promote the product under a one-brand, one-channel, two-promotion scheme.

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

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About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 91,000 people and markets its products in more than 130 countries. In Japan, Abbott employees are devoted to the manufacture, development, distribution, and marketing of pharmaceuticals and medical products, including nutritionals, devices, diagnostics, and products for vision care. Abbott's main offices in Japan are located in Tokyo, Fukui, and Chiba. News releases issued by Abbott Japan and Abbott Headquarters are available at www.abbott.co.jp and www.abbott.com, respectively.

About Eisai, Co., Ltd.

Eisai Co., Ltd. is a research-based pharmaceutical company that discovers, develops and markets products worldwide. Guided by its corporate mission of “giving first thought to patients and their families, and to increasing the benefits that health care provides,” all Eisai employees aspire to meet the various needs of global health care as representatives of a “human health care (*hhc*) company” that is capable of making a meaningful contribution under any health care system. For more information about Eisai Co., Ltd., please visit www.eisai.com.