**FOR IMMEDIATE RELEASE**
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AbbVie GK
Eisai Co., Ltd.

# AbbVie and Eisai Clear All-Case Surveillance Condition for Approval of HUMIRA®, a Fully Human Anti-TNF-α Monoclonal Antibody, in the Treatment of Polyarticular Juvenile Idiopathic Arthritis

- *Japan's Ministry of Health, Labour and Welfare cleared the condition for approval based on a review of an interim report of all-case surveillance on patients with polyarticular juvenile idiopathic arthritis*
- *The analysis results supported the previously established safety and efficacy of HUMIRA®*

AbbVie GK (Headquarters: Tokyo, President: James C. Feliciano, "AbbVie") and Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that they have received notification from Japan's Ministry of Health, Labour and Welfare (MHLW) to the effect that the "all-case surveillance" special drug use-results survey condition required for approval of HUMIRA® Pre-filled Syringe 20 mg / 0.4 mL and HUMIRA® Pre-filled Syringe 40 mg / 0.8 mL (adalimumab; [genetical recombination], "HUMIRA®"), a fully human anti-TNF-α monoclonal antibody formulation, has been lifted for use in patients with polyarticular juvenile idiopathic arthritis (JIA).

In July 2011, the MHLW approved the indication of polyarticular JIA for HUMIRA® with the following condition for approval: "Because of the very limited number of subjects treated in the Japanese clinical trials, the applicant is required to conduct all-case drug use-results survey until data from a certain number of patients are accumulated after market launch, in order to identify the background information of patients treated with the product and collect safety and efficacy data on the product in the early post-marketing period, and thereby take necessary measures to ensure proper use of the product."

The MHLW lifted this condition for approval based on a review of requirements in the approval condition for HUMIRA®, i.e., early collection of the safety and efficacy data on HUMIRA® and necessary measures for its proper use, which were submitted to the MHLW in an interim report of the all-case surveillance in 176 patients with polyarticular JIA. The analysis results supported the previously established safety and efficacy of HUMIRA®. Adverse drug reactions developed in 30.1% of patients (53 of 176), and regarding efficacy, the results observed in the survey were similar to that observed in other clinical studies conducted in Japan to date.

Clinical studies of HUMIRA® have been carried out extensively to date and a wide literature of clinical data exists on the drug. In Japan, AbbVie 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.

AbbVie and Eisai will continue to promote and provide information on the proper use of HUMIRA® while making further contributions to improve the quality of life of patients.

**[Notes to editors]**

**1. Glossary of Terms**

**1) Polyarticular Juvenile Idiopathic Arthritis**

Juvenile idiopathic arthritis (JIA) is an autoimmune disease that generally affects children under 16 years of age and is an umbrella term used to define a group of conditions occurring among children that include some form of chronic arthritis. JIA is the most common form of childhood arthritis. Polyarticular JIA is a type of JIA which involves five or more joints. Symptoms include painful and swollen joints, limping, morning stiffness, decreased activity and the reluctance to use an arm or leg. Early diagnosis and appropriate management of JIA are important in managing this chronic disease.

**2) TNFα**

The tumor necrosis factors (TNFs) are a group of cytokines mediating intercellular communication that have been found to damage tumor cells.

TNFα is produced by many types of cells, including macrophages, lymphocytes, and vascular endothelial cells, and is known to cause and enhance inflammatory responses and to activate inflammatory cells. TNFα, when produced in excess, plays a central role in the inflammatory responses involved in some immune-mediated diseases.

**3) Monoclonal antibody**

A monoclonal antibody is a protein produced from clones of a single antibody-producing cell (known as a monoclone). It is a homologous population of antibody molecules identical in affinity and specificity to the target antigen.

**4) Drug use-results survey**

A drug use-results survey is defined as follows by the MHLW ordinance (Good Post-marketing Study Practice [GPSP] Ministerial Ordinance).

“Among post-marketing surveys, a drug use-results survey refers to a survey by the manufacturing/marketing authorization holder to screen or confirm information related to the incidence of each disease due to adverse drug reactions, together with the quality, efficacy and safety of drugs, without specifying the condition of the patients that use the drugs.”

**5) Special drug use-results survey**

A special drug use-results survey is a type of drug use-results surveys. A special drug use-results survey is defined as follows by the MHLW ordinance (GPSP Ministerial Ordinance). The all-case surveillance condition for approval which was cleared as announced in this press release concerns a special drug use-results survey.

“Among drug use result surveys, special drug use-results survey refers to a survey by the manufacturing/marketing authorization holder to screen or confirm information relating to the incidence of each disease due to adverse drug reactions, together with the quality, efficacy and safety of drugs, in specified populations of patients, such as pediatric patients, elderly patients, pregnant women, patients with renal and/or hepatic disorders, and patients using the drug for long periods, and also to obtain information for the effective and safe use of drugs.”

**2. About HUMIRA®**

HUMIRA® is a fully human anti-TNF-α monoclonal antibody which is approved for the following indications in Japan: "treatment of rheumatoid arthritis (including prevention of structural joint damage) and the following diseases that do not sufficiently respond to existing treatments: psoriasis vulgaris; arthropathic psoriasis; ankylosing spondylitis; polyarticular juvenile idiopathic arthritis; intestinal Behçet's disease; moderate to severe active Crohn's disease as remission induction and maintenance therapy; and moderate to severe ulcerative colitis."

**3. About AbbVie**

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

AbbVie GK was established in Japan in 2013. The company employs 900 people, dedicated to developing and delivering treatments in our therapeutic areas focused on immunology, neonatology, liver disease and neuroscience, where we believe we can make a remarkable impact on the lives of patients. For further information, please visit www.abbvie.co.jp.

**4. About Eisai**

Eisai Co., Ltd. is a Japan-based global research-based pharmaceutical company, and aims to be a "*human health care* (*hhc*)" company that gives first thought to patients and their families, and to increasing the benefits health care provides. Eisai Co., Ltd. has a global network of research facilities, manufacturing sites, and marketing subsidiaries, and approximately 10,000 employees worldwide are engaged in development and provision of innovative new drugs in areas of unmet medical needs. For further information on Eisai Co., Ltd., please visit www.eisai.com.


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