FOR IMMEDIATE RELEASE
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AbbVie GK
Eisai Co., Ltd.
EA Pharma Co., Ltd.

AbbVie, Eisai, and EA Pharma Obtain Additional Approval for New Dosing Regimen of Fully Human Anti-TNF-α Monoclonal Antibody Humira® in Patients with Crohn's Disease

AbbVie GK (Headquarters: Tokyo, President: James Feliciano, "AbbVie"), Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai"), and its subsidiary EA Pharma Co., Ltd. (Headquarters: Tokyo, CEO: Hajime Shimizu, "EA Pharma") today announced the additional approval for a new dosing regimen of Humira® Pre-filled Syringe 40 mg/0.8 mL for Subcutaneous Injection (generic name: adalimumab [recombinant], "Humira"), a fully human anti-TNF-α monoclonal antibody formulation, in patients with moderate or severe Crohn's disease who become less responsive to treatment with 40 mg every two weeks to double the dose to 80 mg every two weeks.

The usual adult dose of Humira for Crohn's disease is: initial dose of 160 mg of adalimumab (recombinant) given subcutaneously (SC) followed by 80 mg SC two weeks after the initial dose, then after four weeks of the initial dose. Thereafter, 40 mg SC is given every two weeks. However, some patients became less responsive during their course of treatment, necessitating therapy aimed at "long-term maintenance of remission" which is the goal of treatment for Crohn's disease. Recently, a Japanese clinical study demonstrated the efficacy of an increased dose of 80 mg every two weeks in patients who become less responsive to the conventional dose. As a result, an additional approval was granted for a change in dosing regimen for these patients.

The Japanese Clinical Study on which the present approval was granted was conducted at 12 trial sites with 28 patients suffering from moderate or severe Crohn's disease who became less responsive to treatment with 40 mg every two weeks. This study was a 52-week open-label study to assess the efficacy and safety of Humira when increased to 80 mg every two weeks in which the primary efficacy evaluation was performed at Week 8. When compared to before dose increase, the percentage of patients who experienced a decrease of 50 or greater in Crohn's Disease Activity Index (CDAI) score was 75.0% at Week 8 of treatment, showing an immediate benefit following dose increase. The benefit was maintained for a long period with the percentage of patients with improved CDAI score being 71.4% at Week 24 and 57.1% at Week 52 of treatment. As for the safety of the increased dose of Humira, the safety profile was comparable to dose observed for conventional treatment with Humira; the increased dose was also well tolerated.

In Japan, AbbVie is the marketing and manufacturing authorization holder for HUMIRA. For the indications in the field of gastrointestinal disease (i.e., ulcerative colitis, Crohn's disease, and intestinal Bechet's disease), AbbVie and EA Pharma, a subsidiary of Eisai, are co-promoting Humira. Abbvie and Eisai are co-promoting Humira for the indications in the fields other than gastrointestinal disease (i.e.,

rheumatoid arthritis, plaque psoriasis, arthropathic psoriasis, ankylosing spondylitis, and juvenile idiopathic arthritis).

AbbVie, Eisai and EA Pharma 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. 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."

[Information being added is indicated by underlining.]
Brand name:
Humira® Pre-filled Syringe 40 mg/0.8 mL for Subcutaneous Injection

Generic name:
Adalimumab (recombinant)

Indications:
Induction and maintenance of remission in patients with moderate or severe active Crohn's disease (only when conventional treatments are poorly effective)

Dosage and administration:
The initial dose of Humira is usually given subcutaneously as 160 mg of adalimumab (recombinant) followed by 80 mg two weeks after the first dose and after four weeks of the initial dose. Thereafter, 40 mg is given subcutaneously every two weeks.
<u>The dose can be increased to 80 mg every two weeks when the patient becomes less responsive.</u>

2. About Crohn's disease

Crohn's disease (CD) is an inflammatory disease characterized by ulcers and/or inflammatory lesions in the gastrointestinal tract and is associated with repeated flares/relapses over its long course; CD is most commonly seen in adolescents in their 10s to 20s.[1] The number of CD patients in Japan is increasing every year, from 128 patients in 1976 to 29,799 in 2013.[1]

3. About CDAI

CDAI stands for Crohn's Disease Activity Index and is a measure for evaluating the disease activity of Crohn's disease. The items from which CDAI score is derived include number of soft stools or diarrhea over the last week, intensity of abdominal pain, and subjective general well-being as well as presence of complications with Crohn's disease, hematocrit, and body weight. CDAI score of 220 to 450 corresponds to moderate to severe disease.

4. 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 1,000 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 .

Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry.

Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2015 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

5. About Eisai

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our *"human health care* (*hhc*)" philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Oncology and Neurology. For further information on Eisai Co., Ltd., please visit www.eisai.com.

6. About EA Pharma

Established in April 2016 through the integration of Eisai's gastrointestinal disease business and AJINOMOTO PHARMACEUTICALS Co., Ltd., EA Pharma is a gastrointestinal specialty pharma with a full value chain including research and development, production and logistics, sales and marketing.
For further information on EA Pharma Co., Ltd., please visit www.eapharma.co.jp.

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[1] Japan Intractable Diseases Information Center website (as of December, 2014)