PRESS RELEASE

May 29, 2020

AbbVie GK
Eisai Co., Ltd.

AbbVie and Eisai Announce an approval for partial changes in the marketing approval of HUMIRA®, a Fully Human Anti-TNFα Monoclonal Antibody, concerning the dosage and administration related to the indication of hidradenitis suppurativa

AbbVie GK (Headquarters: Minato-ku, Tokyo; President: James Feliciano, hereafter "AbbVie") and Eisai Co., Ltd. (Headquarters: Tokyo; CEO: Haruo Naito, hereafter “Eisai”) today announced an approval of partial changes in the marketing approval of HUMIRA® (generic name: adalimumab [recombinant], hereafter “HUMIRA”), a fully human anti- TNFα monoclonal antibody, for additional dosage and administration, specifically, to add an 80mg every-other-week (Q2W) regimen as a treatment option for patients with hidradenitis suppurativa (hereafter “HS”) after the first 4 weeks of treatment.

Previously, the recommended dose of HUMIRA for HS patients was 160 mg in week 0, followed by 80 mg two weeks later, administered by subcutaneous injection. Starting at week 4, HUMIRA should be administered at a dose of 40mg once weekly (QW). Today, a 80mg Q2W regimen has been newly added as a treatment option with efficacy and safety equivalence to those of the 40mg QW regimen. 80mg Q2W is expected to contribute to reducing patients’ burden of injection by reducing the number of administrations by half* and extend the administration interval in comparison to 40mg QW.
*When HUMIRA Subcutaneous Injection 80 mg Syringe 0.8 mL or HUMIRA Subcutaneous Injection 80 mg Pen 0.8 mL is used.

This approval was supported by the results of efficacy and safety evaluations at 80mg Q2W for HUMIRA in a Japanese phase III study (Study M15-573) and the results obtained by simulation with data in clinical

AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064

+1 (847) 938-9190
abbvie.com
35V-1940051

Eisai Co.,Ltd.
Public Relations Department
+81(0)3-3817-5120

pharmacokinetic studies. The Japanese phase III study was a multi-center, open-label, single-arm study to evaluate the efficacy and safety of HUMIRA in Japanese patients with moderate to severe HS.

HUMIRA was designated as an orphan drug for the indication of HS in 2017 and was approved for the first time in Japan for the indication of HS on February 21, 2019. Currently, HUMIRA is the only drug that has an indication for HS in Japan.

HS is a painful, inflammatory skin disease with a chronic course which typically presents after puberty. Inflammatory symptoms are frequently observed in the axillary, inguinal, breast-fold, and gluteal regions. The main symptom is red, swollen boil-like lumps, and the progression of symptoms leads to formation of nodules, abscesses, and even fistulas. Repeated recurrence causes thickening of the affected areas, resulting in scarring.[1] Severe symptoms may limit the patients' daily activities and sometimes force them to stop working.[2] The epidemiology data in Japan is unknown,[3] and the prevalence outside Japan is reported to be 1%.[4] Since the disease is poorly recognized and difficult to diagnose, overseas reports indicate that the average time to definitive diagnosis is seven years, which is longer than that of psoriasis and other inflammatory skin diseases, and patients with HS visit hospitals more often.

AbbVie and Eisai are committed to further contribute to the improvement of QOL of many more patients by making efforts to promote the appropriate use of HUMIRA, including its use for this indication, and to provide information on HUMIRA.

About HUMIRA

HUMIRA® is a fully human anti-TNFα monoclonal antibody. In Japan, it is approved for "the treatment of rheumatoid arthritis (including inhibition of the progression of structural damage); hidradenitis suppurativa; plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis*, intestinal Behçet's disease, and non-infectious intermediate, posterior or panuveitis that are refractory to the conventional therapies; induction and maintenance therapy for moderate to severely active Crohn's disease (limited to cases of inadequate response to conventional

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therapy); and treatment of moderate to severe ulcerative colitis (limited to cases of inadequate response to conventional therapy)."

* HUMIRA for Subcutaneous Injection 20mg Syringe 0.2mL is approved. HUMIRA for Subcutaneous Injection 80mg Syringe 0.8 mL and HUMIRA for Subcutaneous Injection 80mg Pen 0.8 mL are yet to be approved for this indication.

Nonproprietary name:	Adalimumab < Genetical Recombination >
Brand name:	HUMIRA, a fully human anti-TNFα monoclonal antibody, "Subcutaneous Injection 20mg Syringe 0.2 mL, 40mg Syringe 0.4 mL, 80mg Syringe 0.8 mL, 40mg Pen 0.4 mL, 80mg Pen 0.8 mL"

About AbbVie

AbbVie is a global, research and development-based biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, LinkedIn or Instagram.

About Eisai Co., Ltd.

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 Neurology and Oncology. As a global pharmaceutical company, our mission extends to patients around the world through our investment and participation in partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit www.eisai.com.

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AbbVie Forward-Looking Statements

Some statements in this news release are, or may be considered, 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 2019 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.

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Contact Information:

AbbVie GK Public Affairs Yuriko Yagi
TEL: 03-4577-1112

Eisai Co., Ltd. PR
TEL: 03-3817-5120