



FOR IMMEDIATE RELEASE

March 23, 2018

AbbVie GK
Eisai Co., Ltd.

AbbVie and Eisai Obtain Additional Approval for New Indication of Fully Human Anti-TNF- α Monoclonal Antibody HUMIRA[®] in the Treatment of Patients who have had an Inadequate Response to Conventional Therapy for Pustular Psoriasis

AbbVie GK (Headquarters: Tokyo, President: James Feliciano, "AbbVie") and Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") today announced the additional approval for a new indication of HUMIRA[®] (generic name: adalimumab [recombinant], "HUMIRA"), a fully human anti-TNF- α monoclonal antibody formulation, in the treatment of patients who have had an inadequate response to conventional therapy for pustular psoriasis. With this approval, HUMIRA has been approved for 10 indications in Japan.

The approval of this additional indication is based on the results of a Phase 3 study in Japanese patients. This study examined efficacy and safety in Japanese patients diagnosed with generalized pustular psoriasis (GPP) who have had an inadequate response to conventional therapy (e.g., etretinate and cyclosporine). Among the patients treated with HUMIRA in the open-label clinical trial, 70% (n=7/10) achieved a clinical response (improvement or reduction of skin score relative to the baseline) after 16 weeks of treatment¹. Adverse reactions were observed in 30% (n= 3/10) of patients, such as eosinophilia, bacterial colitis, herpes zoster infection, and eye contusion (respective incidence was 10% (n=1/10) each). No new safety risks were identified for patients with GPP treated with HUMIRA².

Pustular psoriasis is a disease designated as an "Intractable Disease" by the Japan Ministry of Health, Labor and Welfare (MHLW), and the major symptoms include fever, general malaise, redness, swelling of limbs, and pustules on the whole body. The number of patients receiving intractable disease benefits due to this condition is reported to be 2,072 nationwide, and this has increased by more than 200 patients in the past 5 years (as of the end of fiscal 2016)³. The treatment guideline⁴ for pustular psoriasis includes anti-TNF- α antibody formulations as a treatment option alongside etretinate, methotrexate, and cyclosporine.

"The research and clinical technology on GPP have been evolving dramatically in the recent years. However, further progress is needed considering severity of the disease. The approval of this

indication for HUMIRA has been highly anticipated by healthcare professionals as well as patients,” said Hidemi Nakagawa, M.D., Chair, Department of Dermatology, The Jikei University School of Medicine.

“We are pleased to provide the new treatment option to patients with pustular psoriasis,” said James Feliciano, President of AbbVie Japan. “More than 1 million patients have been already treated with HUMIRA in more than 100 countries. This is the 10th indication of HUMIRA approved on the 10th anniversary of its first launch in Japan. We continue to contribute to patients living with inflammatory autoimmune diseases by pursuing new discoveries and better outcomes that go beyond current standards of care.”

Mr. Hideki Hayashi, Eisai Representative Corporate Officer, Japan Business and CIO commented, “Eisai will continue to provide healthcare professionals with information and promote proper clinical use, aiming to fulfill the unmet medical needs in the treatment of GPP and maximize benefits for patients and their families.”

[Notes to editors]

1. Summary of Product Characteristics

[Extract of relevant items, information being added is indicated by underlining]

1) Brand name:

HUMIRA® for Subcutaneous Injection 40 mg syringe 0.8 mL

HUMIRA® for Subcutaneous Injection 40 mg syringe 0.4 mL

HUMIRA® for Subcutaneous Injection 80 mg syringe 0.8 mL

HUMIRA® for Subcutaneous Injection 40 mg pen 0.4 mL

HUMIRA® for Subcutaneous Injection 80 mg pen 0.8 mL

2) Generic name:

Adalimumab (recombinant)

3) Indications:

Patients who have had an inadequate response to conventional therapy for pustular psoriasis

4) Dosage and administration:

Normally, the dose of adalimumab (genetic recombination) for adult patients with GPP is an initial dose of 80 mg followed by 40 mg given every other week (eow) starting 2 weeks after the initial dose as subcutaneous injection. The dose may be increased to 80 mg eow when the effect of treatment with 40 mg eow is insufficient.

2. Summary of Safety Information

1) Contraindications

- (1) Patients with serious infection (sepsis etc.)
- (2) Patients with active tuberculosis
- (3) Patients having a history of hypersensitivity to any of the ingredients of HUMIRA
- (4) Patients having a current or past history of demyelinating disorder (multiple sclerosis, etc.)
- (5) Patients with congestive heart failure

2) Adverse Reactions

In clinical studies of rheumatoid arthritis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis, juvenile idiopathic arthritis, gastrointestinal Behçet's disease, Crohn's disease, ulcerative colitis, and non-infectious intermediate uveitis, posterior uveitis or panuveitis, 82.5% (n=1,079/1,308) of Japanese safety evaluation population experienced adverse reactions. Among them, main symptoms were nasopharyngitis 29.7% (n=389), injection site erythema 9.6% (n=126), injection site reactions 8.5% (n=111), rash 7.5% (n=98), and upper respiratory infection 6.3% (n=83).

About AbbVie

AbbVie is a global, research-driven 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](https://twitter.com/abbvie) on Twitter, [Facebook](https://www.facebook.com/abbvie) or [LinkedIn](https://www.linkedin.com/company/abbvie).

For more information, please visit www.abbvie.com/HCV.

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.

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 2016 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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- 1 Drug Information of HUMIRA
 - 2 Data on file
 - 3 Intractable Disease Information Center (<http://www.nanbyou.or.jp/>)
 - 4 Pustular Psoriasis (Generalized) Guideline 2014, GPP Clinical Guideline Committee, Japanese Dermatological Association, *Japanese Dermatological Association Journal*: 125(12),2211-2257,2015