PRESS RELEASE

AbbVie and Eisai Announce Fully Human Anti-TNF-α Monoclonal Antibody HUMIRA® is the First in Japan to be Approved for the Treatment of Hidradenitis Suppurativa

TOKYO, February 21st, 2019 – AbbVie, a research-based global biopharmaceutical company, (Headquarters: Minato-ku, Tokyo, President: James Feliciano) and Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") today announced that they have received approval for an additional indication of HUMIRA® (generic name: adalimumab [recombinant], "HUMIRA"), a fully human anti-TNF-α monoclonal antibody, for the treatment of hidradenitis suppurativa (HS). With this approval, HUMIRA has become the first treatment indicated for HS in Japan, and is now approved for 11 indications in Japan.

The approval of this additional indication is based on the data from a Japanese Phase III study[1] and overseas clinical trials.[2] In these trials, the efficacy and safety of HUMIRA were evaluated in patients with moderate to severe HS. In the clinical trial conducted in Japan, the percentage of patients who achieved the primary endpoint of HiSCR* at Week 12 after treatment was 13 of 15 patients.[3] In the same trial, adverse drug reactions (ADRs) were observed in 6 of 15 patients at Week 24 of treatment; ADRs observed in two or more patients were nasopharyngitis and cellulitis, and other ADRs including dental caries, erythrasma, folliculitis, lymphocyte count increased, erythema, pruritus, and skin exfoliation were observed in one patient each.[3]

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.[4] Severe symptoms may limit the patients' daily activities and sometimes force them to stop working.[5] The epidemiology data in Japan is unknown,[6] and the prevalence outside Japan is reported to be 1%.[7]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.

"This approval will be a major step for patients with HS. HS is a recurrent disease with pain and pus discharge. It has a significant impact on patients' quality of life, affecting their work or study performance and, in advanced cases, requiring major surgery with skin grafting," said Dr. Tadashi Terui, Professor, Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine. "Only limited options have been available for the treatment of HS until now. The additional indication of HUMIRA for HS is expected to significantly contribute to the improvement in patients' quality of life."

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.

* HiSCR stands for Hidradenitis Suppurativa Clinical Response, and is defined as at least a 50% reduction from baseline in the abscess and inflammatory nodule counts, with no increase in abscess or draining-fistula counts.

About HUMIRA

HUMIRA® is a fully human anti-TNF-α monoclonal antibody formulation. In Japan, it is approved for the indications of "the treatment of rheumatoid arthritis (including inhibition of the progression of structural damage), the treatment of plaque psoriasis, arthritic psoriasis, pustular psoriasis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis,** intestinal Behçet's disease, non-infectious uveitis, posterior uveitis or panuveitis, induction and maintenance therapy for moderate to severely active Crohn's disease (administer HUMIRA to patients who have had an inadequate response to conventional therapy), and treatment of moderate to severe ulcerative colitis (administer HUMIRA to patients who have had an inadequate response to conventional therapy)."

**: HUMIRA® for Subcutaneous Injection 80 mg Syringe 0.8 mL and HUMIRA® for Subcutaneous Injection 80 mg Pen 0.8 mL are yet to be approved for this indication.
Only HUMIRA® for Subcutaneous Injection 20 mg Syringe 0.4 mL and HUMIRA® for Subcutaneous Injection 20 mg Syringe 0.2 mL are approved for this indication.

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 on Twitter, Facebook or LinkedIn.

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.

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 over 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 in various therapeutic areas with high unmet medical needs, including Neurology and Oncology.

Furthermore, we invest and participate in several 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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1. ClinicalTrials.gov Identifier: NCT02904902
2. ClinicalTrials.gov Identifier: NCT01468207, NCT01468233
3. Annual Meeting of the Tokyo Division of JDA, 2nd December, 2018
4. Hunger RE, et al. Dermatology. 2017 Jul 7. doi: 10.1159/000477459.
5. Jemec G. Clinical and experimental dermatology. , 1996, Vol.21(6), p.419-423
6. Nobukazu Hayashi et.al., Journal of the Japan Organization of Clinical Dermatologists, 35（4）;601-609, 2018
7. Revuz J., J Eur Acad Dermatol Venereol. 2009 Sep;23(9):985-98.

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