PRESS RELEASE

November 27, 2020

AbbVie GK
Eisai Co., Ltd.

AbbVie and Eisai Announce an approval for additional indication of HUMIRA®, a fully Human Anti-TNFα Monoclonal Antibody, for the treatment of pyoderma gangrenosum for the first time in the world

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 additional indication of HUMIRA® (generic name: adalimumab [recombinant], hereafter "HUMIRA"), a fully human anti-TNFα monoclonal antibody, for the treatment of pyoderma gangrenosum (hereafter "PG"). HUMIRA was granted orphan drug designation for the treatment of PG in 2019. This indication counts for HUMIRA's 12th indication in Japan and makes HUMIRA the world's first drug indicated for the treatment of PG.

This approval of the additional indication is based on the data from the Japanese phase III clinical trial[1] conducted in Japanese patients. This study was conducted to evaluate the efficacy and safety of HUMIRA targeting the patients with active ulcers in Japan who were diagnosed with PG but were not sufficiently effective with local treatment, or who were judged to be unsuitable for local treatment. The proportion of patients achieving at 100 (targeted PG ulcer healed) of the target pyoderma gangrenosum ulcer area reduction (PG Area Reduction: PGAR) at Week 26 of administration, which is the primary endpoint of this trial, was 54.5% (12 of 22 patients)[1]. The most common adverse drug reactions in patients receiving HUMIRA were skin bacterial infection[1].

PG is an inflammatory skin disease that rapidly progresses after its onset and is classified into the following 5 types: ulcerative type, bullous type, pustular type, vegetative type, and a type that develops around a stoma[2]. In ulcerative PG, the most common type, appears as painful, pustules, papules and nodules in the

lower extremities, especially in the lower legs, and efferently expands to form raised ulcer lesions with infiltration on the margins[3]. The ulceration accompanied by intense pain and is known to cause serious effects on patients' quality of life (QOL)[4]. Although the pathogenic mechanism of PG is not fully understood, it is reported that approximately 20-30% of PG cases are caused by a slight injury or an external stimulus[5]. PG mostly affects people in their 50s to 70s, and its incidence is reported to be 3.0 per million/year in Japan[6].

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-TNF-α monoclonal antibody. In Japan, it is approved for "the treatment of rheumatoid arthritis (including inhibition of the progression of structural damage); hidradenitis suppurativa, the treatment of plaque psoriasis, arthritic psoriasis, pustular psoriasis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis*, intestinal Behçet's disease, and non-infectious intermediate, posterior and panuveitis that are refractory to the conventional therapies, induction and maintenance therapy for moderate to severely active Crohn's disease (limited to patients who have had an inadequate response to conventional therapy), and treatment of moderate to severe ulcerative colitis (limited to patients who have had an inadequate response to conventional therapy)."

* HUMIRA for Subcutaneous Injection 20 mg Syringe 0.2 mL is approved. 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.

Nonproprietary name: Adalimumab <recombinant>

Brand name: Fully Human Anti- TNF- α Monoclonal Antibody "HUMIRA for Subcutaneous Injection 20 mg Syringe 0.2 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; and HUMIRA for Subcutaneous Injection 80 mg Pen 0.8 mL"

About AbbVie

AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com. Follow @abbvie on Twitter, Facebook, Instagram, YouTube and LinkedIn.

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 https://www.eisai.com

###

1. ClinicalTrials.gov Identifier: NCT03311464. Unpublished data on file.
2. Yamamoto T: J Dermatol, 130(6), 1439-1448, 2020
3. Idemitsu T. Medical diseases seen in 110 cases of skin symptoms:7(4), 138-139, 2018
4. Ormerod AD, Thomas KS, Craig FE, Mitchell E, Greenlaw N, Norrie J, Mason JM, Walton S, Johnston GA, Williams HC; UK Dermatology Clinical Trials Network's STOP GAP Team.. BMJ.2015 Jun 12; 350: h2958. doi: 10.1136/bmj.h2958.
5. Callen JP, Jackson JM: Pyoderma gangrenosum: an update, Rheum Dis Clin North Am, 2007; 33: 787—802.
6. Yamamoto T: J Dermatol, 46: e145-e146, 2019

Contact Information:

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

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