



PRESS RELEASE

AbbVie and Eisai Announce the Launch of HUMIRA[®] for Subcutaneous Injection 20 mg Syringe 0.2 mL, A New Pediatric Formulation of HUMIRA[®]

TOKYO, June 21, 2018 – AbbVie GK (Headquarters: Tokyo, President: James Feliciano, “AbbVie”) and Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced that HUMIRA[®] for Subcutaneous Injection 20 mg Syringe 0.2 mL, a new pediatric formulation of HUMIRA[®] (generic name: adalimumab [recombinant], “HUMIRA”), a fully human anti-TNF- α monoclonal antibody formulation, has been launched today after being listed in the National Health Insurance reimbursement price list on June 15.

HUMIRA has an indication of “treatment of polyarticular juvenile idiopathic arthritis (JIA)” that develops in pediatric patients.

HUMIRA[®] for Subcutaneous Injection 20 mg Syringe 0.2 mL is a higher-concentration formulation, which is produced by removing some excipients, and has the same active ingredient as that of, HUMIRA[®] for Subcutaneous Injection 20 mg Syringe 0.4 mL that has been commercially available since September 2011. It has also the same formulation and concentration as those of HUMIRA[®] for Subcutaneous Injection 40 mg Syringe 0.4 mL and HUMIRA[®] for Subcutaneous Injection 80 mg Syringe 0.8 mL that were launched in November 2016. Outside of Japan, two phase 2, randomized, single-blind, two-period crossover studies were conducted with HUMIRA[®] for Subcutaneous Injection 40 mg Syringe 0.4 mL, to compare injected site-related pain between this higher-concentration formulation and the former formulation, using a visual analog scale (VAS). Patients with rheumatoid arthritis showed a significantly lower VAS pain score after injection of the higher-concentration formulation, as compared with the former formulation.

JIA is an autoimmune disease that generally affects children under 16 years of age and is an umbrella term used to define a group of conditions occurring among children that include some form of chronic arthritis. In Japan, JIA affects 10-15 persons per 100,000 children, and is designated as an incurable disease by the Ministry of Health, Labour and Welfare. Polyarticular JIA is a type of JIA which involves five or more joints. Symptoms include painful and swollen joints, limping, morning stiffness, decreased activity and the reluctance to use an arm or leg.

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 including children.



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, and non-infectious uveitis, posterior uveitis or panuveitis, 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 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.

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).

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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Media Inquiries:

Public Affairs Division, AbbVie GK
+81-(0)3-4577-1112

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