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AbbVie GK
Eisai Co., Ltd.

AbbVie and Eisai Announce HUMIRA® Pre-filled Syringe Has Received Approval for the Treatment of Intestinal Behçet's Disease in Japan

HUMIRA is the First Biologic Approved to Treat Intestinal Behçet's Disease in Japan

AbbVie GK (Headquarters: Tokyo, President: Gary M. Winer, "AbbVie") and Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, "Eisai") today announced that they have received indication approval for the treatment of intestinal Behçet's disease for HUMIRA® Pre-filled Syringe 40 mg / 0.8 mL (adalimumab; recombinant, "HUMIRA"), a fully human anti-TNF-α monoclonal antibody formulation. This latest approval makes HUMIRA the first biologic to have been indicated for intestinal Behçet's disease in Japan.

Behçet's disease is a chronic, systemic inflammatory disease characterized by clinical symptoms such as recurrent aphthous stomatitis, skin manifestations, eye inflammation and genital ulcers. In Japan, the treatment of Behçet's disease is covered under the Specified Disease Treatment Research Program. As of March 2012, more than 18,000 patients with Behçet's disease had received treatment under this program. Behçet's disease accompanied by intestinal ulcer, which occurs in 10-15% of the total patients, is referred to as intestinal Behçet's disease.

HUMIRA is now indicated for seven diseases for the treatment of immune-mediated inflammatory diseases in Japan, including rheumatoid arthritis (including inhibition of structural damage), plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, Crohn's disease, and intestinal Behçet's disease.

AbbVie is the marketing and manufacturing authorization holder of HUMIRA in Japan and Eisai is responsible for its distribution. Both companies work together to help address significant unmet medical and patient needs, and provide HUMIRA as a new treatment for intestinal Behçet's disease.

[See the reference information for a product outline, glossary of terms, introductions to HUMIRA and AbbVie, and AbbVie and Eisai's respective commitments to immunology.]

Media Inquiries	
Department of Public Affairs AbbVie GK Phone 03-4577-1112	Public Relations Department Eisai Co., Ltd. Phone 03-3817-5120

1. **HUMIRA® Pre-filled Syringe 40 mg / 0.8 mL product outline (new prescription information underlined)**

1) Indications

Rheumatoid arthritis (including inhibition of structural damage)

Patients who have had an inadequate response to conventional therapy for the following diseases:
Plaque psoriasis and psoriatic arthritis
Ankylosing spondylitis
Juvenile idiopathic arthritis with active polyarthritis
Intestinal Behçet's disease

Induction and maintenance therapy for moderate to severely active Crohn's disease (restricted to patients who have had an inadequate response to conventional therapy)

2) Dosage and administration

Rheumatoid arthritis

The dose of adalimumab (recombinant) for adult patients is 40 mg administered every other week (eow) as a subcutaneous injection. The dose may be increased to 80 mg administered eow when the effect of treatment with 40 mg eow is insufficient.

Plaque psoriasis and psoriatic arthritis

The dose of adalimumab (recombinant) for adult patients is an initial dose of 80 mg followed by 40 mg administered eow starting two weeks after the initial dose, with both dosages administered as a subcutaneous injection. The dose may be increased to 80 mg administered eow when the effect of treatment with 40 mg eow is insufficient.

Ankylosing spondylitis

The dose of adalimumab (recombinant) for adult patients is 40 mg administered eow as a subcutaneous injection. The dose may be increased to 80 mg administered eow when the effect of treatment with 40 mg eow is insufficient.

Juvenile idiopathic arthritis with active polyarthritis

The dose of adalimumab (recombinant) for patients with juvenile idiopathic arthritis who weigh over 15 kg but less than 30 kg is 20 mg administered eow and for patients weighing 30 kg or more is 40 mg administered eow as a subcutaneous injection.

Intestinal Behçet's disease

The dose of adalimumab (recombinant) for adult patients is an initial dose of 160 mg followed by 80 mg administered two weeks later, with both dosages administered as a subcutaneous injection. Four weeks after the initial dose begin 40 mg administered eow as a subcutaneous injection.

Crohn's disease

The dose of adalimumab (recombinant) for adult patients is an initial dose of 160 mg followed by 80 mg administered two weeks later, with both dosages administered as a subcutaneous injection. Four weeks after the initial dose begin a maintenance dose of 40 mg administered eow as a subcutaneous injection.

2. **Glossary of terms**

1) Intestinal Behçet's disease

Behçet's disease (BD), a systemic inflammatory disease that is characterized by aphthous stomatitis, skin symptoms, eye symptoms, and genital ulcers, is often associated with episodes of acute inflammation during its chronic course. BD is prevalent in Asia, the Middle East, and the Mediterranean region, but is quite rare in Europe and the United States. The prevalence of BD in Japan is relatively high, and as of end of March 2012, more than 18,000 patients with BD in Japan are covered by the Specified Disease Treatment Research

Program. BD develops in males and females in their late 20s to 40s, who are in their most productive years. Although the etiology of BD is still unknown, involvement of specific genetic factors is suspected since the prevalence of HLA-B51, a major histocompatibility complex class I antigen, is high among patients with BD.

Patients with BD may experience intestinal symptoms such as abdominal pain, abdominal discomfort, and diarrhea, and may have ulcers in the ileocecum, which is located in the right lower abdomen, in addition to the above-mentioned four main clinical findings. BD associated with intestinal signs/symptoms is referred to as intestinal BD. When intestinal ulcers are worsened, intestinal bleeding and perforation may develop and require urgent surgery.

2) TNF-α

The tumor necrosis factors (TNFs) are a group of cytokines (i.e., substances mediating cell-cell interactions) mediating intercellular communication that have been found to damage tumor cells. TNF-α is produced by many types of cells, including macrophages, lymphocytes, and vascular endothelial cells, and is known to cause and enhance inflammatory responses and to activate inflammatory cells.

3) Monoclonal antibody

A monoclonal antibody is a protein produced from clones of a single antibody-producing cell (called a monoclone). Using the monoclonal antibody technique, manufacturers can obtain a homologous population of antibody molecules identical in amino acid sequence and other characteristics.

3. About HUMIRA®

HUMIRA® has been approved in Japan for rheumatoid arthritis (April 2008), plaque psoriasis and psoriatic arthritis (January 2010), Crohn's disease (October 2010), ankylosing spondylitis (October 2010), juvenile idiopathic arthritis (July 2011), and intestinal Behçet's disease (May 2013). And "including inhibition of structural damage" was added to the indication of "rheumatoid arthritis" on August 2012.

4. AbbVie's commitment to immunology

AbbVie is focused on the discovery and development of innovative treatments for immunologic diseases. The Abbott Bioresearch Center, founded in 1989 in Worcester, Mass., the United States, is a world-class discovery and basic research facility committed to finding new treatments for autoimmune diseases.

More information about HUMIRA®, including full prescribing information, is available on the Web sites http://www.e-HUMIRA.jp (Japanese only) and www.HUMIRA.com (English).

5. Eisai's commitment to immunology

Eisai, whose strength lies in low-molecular-weight drugs, is aggressively addressing the development of biologics. KAN product creation unit located in the area of both Kobe and Tsukuba commits to discover appropriate drug targets using cellomics technology and create antibodies for those targets. Having acquired Morphotek Inc., a U.S. bioventure specialized in the research and development of antibody drugs, in April 2007, Eisai is now involved in the creation of antibody drugs for the treatment of cancer, rheumatoid arthritis, and infectious diseases using Morphotek's proprietary technologies, such as Human Morphodoma® and Libradoma™. In addition, Eisai is working with Sweden-based BioArctic Neuroscience Inc. to investigate potential immunotherapies for Alzheimer's disease, and while AbbVie GK is the marketing and manufacturing authorization holder of HUMIRA® in Japan and Eisai is responsible for its distribution, the two companies are working together to promote the drug. Through these collaborations and other activities, Eisai seeks to make further contributions to improving the quality of life of patients and their families through the development and production of antibody drugs.

6. **About AbbVie**

AbbVie (NYSE:ABBV) is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott. AbbVie combines the focus and passion of a leading-edge biotech with the expertise and capabilities of a long-established pharmaceutical leader to develop and market advanced therapies that address some of the world's most complex and serious diseases. In 2013, AbbVie will employ approximately 21,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @AbbVie on Twitter or view careers on our Facebook page.