June 14, 2013

AbbVie GK
Eisai Co., Ltd.

AbbVie and Eisai Announce HUMIRA® Pre-filled Syringe 40 mg / 0.8 mL, a Fully Human Monoclonal Anti-TNF-α Antibody Formulation, Has Received Approval for the Treatment of Moderate to Severe Ulcerative Colitis (UC) in Japan

HUMIRA Becomes the First and Only Self-Injectable Biologic Therapy for the Treatment of Moderate to Severe UC

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 ulcerative colitis (UC) for HUMIRA® Pre-filled Syringe 40 mg / 0.8 mL (adalimumab; recombinant, "HUMIRA"), a fully human anti-TNF-α monoclonal antibody formulation.

UC is a refractory disease that causes inflammation in the colon and rectum. The symptoms of UC, which may include diarrhea and abdominal pain, tend to come and go and may significantly impact the quality of life of patients. The Ministry of Health, Labor and Welfare has designated UC as a specified disease, for which financial support is provided for relevant healthcare services. The number of patients with UC in Japan (patients receiving treatment for UC under the Specified Disease Treatment Research Program) amounts to more than 130,000 and this figure increases every year by approximately 8,000 patients[1], leaving unmet medical needs for the effective treatment of this disease.

"Ulcerative colitis is accompanied with digestive symptoms including diarrhea and abdominal pain that can significantly affect the lives of patients and may lead to hospitalizations or operations," said Professor Mamoru Watanabe, Department of Gastroenterology and Hepatology, Tokyo Medical and Dental University. "Having HUMIRA as a treatment option for ulcerative colitis is great news for patients and for physicians. HUMIRA is the only self-injectable biologic approved for the treatment of moderate to severe ulcerative colitis and it will be welcomed by patients as a convenient treatment."

HUMIRA is now indicated for eight 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, intestinal Behçet's disease and UC.

AbbVie is the marketing and manufacturing authorization holder of HUMIRA in Japan and Eisai is responsible for its distribution. The two companies jointly promote the product under a single brand name, HUMIRA.

AbbVie and Eisai remain committed to working together to help address significant unmet medical and patient needs, and to provide HUMIRA as a new treatment for UC.

[Please refer to the following notes for a product outline, glossary of terms, introductions to HUMIRA and AbbVie, and AbbVie and Eisai's respective commitments to immunology.]

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[Notes to editors]

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)

Treatment of moderate to severe ulcerative colitis (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 40 mg administered eow as a subcutaneous injection.

Ulcerative colitis

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.

2. Glossary of terms

1) Ulcerative colitis (UC)

UC is a chronic inflammatory bowel disease that causes inflammation in the rectum and colon, resulting in frequent diarrhea, rectal bleeding and abdominal cramping. The symptoms of UC tend to come and go, with varying periods of clinical stability. The number of patients with UC in Japan (patients receiving treatment for UC under the Specified

Disease Treatment Research Program) amounts to more than 130,000 and this figure increases every year by approximately 8,000 cases[1].

2) TNF-α

The tumor necrosis factors (TNFs) are a group of cytokines 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 the treatment of 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), intestinal Behçet's disease (May 2013) and ulcerative colitis (June 2013). Furthermore, "including inhibition of structural damage" was added as an indication for rheumatoid arthritis in 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 (in Japanese only) and www.HUMIRA.com (in English).

5. Eisai's commitment to immunology

Eisai, whose strengths include low-molecular-weight drugs, is aggressively addressing the development of biologics. The KAN Product Creation Unit, located in Kobe and Tsukuba, is committed to discovering 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, both AbbVie GK and Eisai 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.

Reference

[1] Japan Intractable Disease Information Center website (As of April 2013)