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Press Release

Abbott Japan Co., Ltd.
Eisai Co., Ltd.

Abbott Japan and Eisai Submit Application for Additional Indication of Humira[®], a Fully Human Anti-TNF α Monoclonal Antibody, for the Treatment of Juvenile Idiopathic Arthritis in Japan

Abbott Japan Co., Ltd. (Pharmaceutical Products Group Headquarters: Tokyo, President: Gary M. Winer, "Abbott Japan") and Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that they have submitted an application to the Japanese Ministry of Health, Labour and Welfare seeking approval of juvenile idiopathic arthritis (JIA) as an additional indication for Humira[®] pre-filled syringe 40 mg/0.8 mL for subcutaneous injection (generic name: adalimumab [genetical recombination]), a fully human anti-TNF α monoclonal antibody jointly developed by the two companies in Japan. If and when approved, JIA will be the fifth approved indication for Humira[®], following rheumatoid arthritis (approved in April 2008), plaque psoriasis and psoriatic arthritis (approved in January 2010), Crohn's disease (filed for approval in September 2009), and ankylosing spondylitis (filed for approval in October 2009).

In addition to the application for approval of the additional indication, the two companies also submitted an application for approval of Humira[®] pre-filled syringe 20 mg/0.4 mL for use in JIA patients of low body weight.

Humira[®] is a fully human anti-TNF α monoclonal antibody that exerts its effects by neutralizing TNF- α , a cytokine that plays a central role in inflammatory responses. While Abbott Japan is the marketing authorization holder of Humira[®] in Japan and Eisai is responsible for its distribution, the two companies are working together to promote the drug.

In multi-institutional collaborative studies conducted in Japanese patients with JIA, Humira[®] demonstrated excellent efficacy in improving the signs and symptoms of JIA and tolerability equivalent to that observed in foreign studies.

JIA is an autoimmune disease that generally affects children under 16 years of age and is the most common pediatric rheumatic disease, a category of diseases that includes JIA, systemic lupus erythematosus, dermatomyositis, and polymyositis. In an effort to make contributions to improving their quality of life (QOL), Abbott Japan and Eisai will work in tandem to deliver Humira[®] as a new treatment option to patients living with JIA.

[Please refer to the following notes for a glossary of terms, product and company information, and an outline on Eisai and Abbott's Commitment to Immunology]

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[Notes to editors]

1. Glossary of Terms

1) Juvenile idiopathic arthritis (JIA)

JIA is an autoimmune disease that generally affects children under 16 years of age and is the most common pediatric rheumatic disease, a category of diseases that includes JIA, systemic lupus erythematosus, dermatomyositis, and polymyositis. Although the etiology of JIA is still unclear, JIA is believed to be a multifactorial disease caused by a complex combination of genetic and environmental factors. It is also thought that TNF and other proinflammatory cytokines are produced excessively in the joints of patients with JIA and trigger inflammatory reactions the same as those observed in adult patients with rheumatoid arthritis. Previously termed juvenile rheumatoid arthritis, JIA is a chronic form of childhood arthritis that is classified into seven subtypes, including systemic JIA, oligoarticular JIA, rheumatoid factor-negative polyarticular JIA, and rheumatoid factor-positive polyarticular JIA. It is mainly treated with non-steroidal antiinflammatory drugs and low-dose methotrexate pulse therapy.

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. TNF α , when produced in excess, plays a central role in the inflammatory responses of some immune-mediated diseases.

3) Monoclonal antibody

A monoclonal antibody is a protein produced from clones of a single antibody-producing cell (known as a monoclonal). It is a homologous population of antibody molecules identical in affinity and specificity to the target antigen.

2. About Humira®

Humira® resembles antibodies normally found in the human body. It works by blocking tumor necrosis factor alpha (TNF α), a protein that plays a central role in inflammatory responses.

As of June 2010, Humira® has been approved for the treatment of rheumatoid arthritis in 86 countries, psoriatic arthritis in 79 countries, ankylosing spondylitis in 76 countries, Crohn's disease in 75 countries, plaque psoriasis in 75 countries, and JIA in 50 countries, and more than 460,000 people worldwide have been treated with it.

Humira® has been extensively investigated in a wide range of clinical studies, and a large-scale safety information database has been established containing data on approximately 24,000 patients who received adalimumab for a variety of indications between April 1, 1997 and November 6, 2009. A number of clinical trials are also underway to evaluate the potential of Humira® in treating immune-mediated diseases other than those for which it is currently indicated.

3. Eisai's Commitment to Immunology

Eisai, whose strength lies in low-molecular-weight drugs, is aggressively addressing the development of biologics. Having acquired Morphotek, Inc., a U.S. bio-venture 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 is developing and marketing Humira®, a fully human anti-TNF α monoclonal antibody, in Japan in cooperation with Abbott Japan, thus demonstrating its commitment to improving the quality of life (QOL) of patients and their families by producing antibody drugs.

4. About Abbott

Headquartered in Chicago, Illinois, Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 83,000 people and markets its products in more than 130 countries.

In Japan, approximately 2,500 Abbott employees are devoted to the manufacture, development, distribution, and marketing of pharmaceuticals and medical products, including nutritionals, devices, diagnostics, and products for vision care. Abbott's main offices in Japan are located in Tokyo, Fukui, and Chiba. News releases issued by Abbott Japan and Abbott Headquarters are available at www.abbott.co.jp and www.abbott.com, respectively.

5. Abbott's Commitment to Immunology

Abbott is focused on the discovery and development of innovative treatments for immunologic diseases. The Abbott Bioresearch Center, founded in 1989 in Worcester, Mass., 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).