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For Press

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

Abbott Submits Marketing Authorization Application of Humira® (adalimumab), a Fully Human Monoclonal anti-TNF-α Antibody, for the Treatment of Ankylosing Spondylitis in Japan

Abbott Japan Co., Ltd. (Pharmaceutical Products Group, Tokyo, President: Glenn S. Warner, “Abbott Japan”) and Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, “Eisai”) today announced that they had submitted an application for approval for the treatment of ankylosing spondylitis as an additional indication for Humira® pre-filled syringe 40 mg/0.8 mL for subcutaneous injection (generic name: adalimumab), a fully human monoclonal anti-TNF-α antibody jointly developed by the two companies in Japan. If approved, ankylosing spondylitis will be the fourth indication for Humira, following rheumatoid arthritis (approved in April 2008), psoriasis vulgaris and psoriatic arthritis (filed for approval in September 2007), and Crohn's disease (filed for approval in September 2009).

Adalimumab is a monoclonal antibody that neutralizes the activity of tumor necrosis factor alpha (TNF-α), a protein that plays a central role in inflammatory reactions in patients with autoimmune diseases. Abbott Japan obtained marketing authorization for Humira in Japan, while Eisai has approval to distribute the drug. The two companies are co-promoting Humira using a one-brand, one-channel, two- promotion mode.

In clinical studies in patients with active ankylosing spondylitis in Japan, Humira demonstrated excellent efficacy in improving the signs and symptoms of ankylosing spondylitis and tolerability equivalent to that observed in foreign studies.

Ankylosing spondylitis is characterized by joint pain and stiffness in the neck, lower back, and hips, as well as the hands and feet in some cases, followed by the development of fusion and rigidity of affected joints over time. There is no specific cure for this chronic inflammatory disease at this moment. In an effort to contribute to improving the quality of life (QOL) of patients with ankylosing spondylitis, Abbott Japan and Eisai will work in tandem to bring Humira as a new treatment option for them.

[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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1. Glossary

1) Ankylosing spondylitis

Ankylosing spondylitis (AS) is a chronic inflammatory disease that manifests first as joint pain and stiffness in the neck, lower back, and hips, as well as hands and feet in some cases, followed by fusion and rigidity of affected joints over time. In rare cases, severe AS with bony ankylosis of the spine and other joints may develop. Typically, AS develops in young individuals, often men, in their teens and twenties, and progresses slowly over several decades. Although the cause of AS is unknown, it is believed that immunological factors and other factors such as infection with specific bacteria play important roles in causing an immune disorder which induces inflammation of the ligaments and tendons where they attach to bone and eventually rigidity of the spine and other joints. The prevalence of AS differs among ethnic groups, and is lower in Japanese than Caucasians. This is believed to be related to the difference in prevalence of the HLA-B27 genotype in the general population of North America, where it is 7%, and that in Japan, where it is 0.3%. More than 90% of patients with AS have the HLA-B27 genotype. Patients with AS are typically negative for rheumatoid factor.

The most commonly observed initial signs/symptoms of AS are inflammation of ligaments and tendons at their attachments to bone. Affected joints mainly include those of the spine, sacroiliac joints, and joints between the trunk and the extremities such as the shoulder joints and hip joints. Inflammation of affected ligaments and tendons is followed by severe degeneration of tissues. Regeneration of degenerated tissue to normal tissue does not occur, and instead calcification or ossification develops, eventually inducing fusion of joint bone tissues and resulting in complete rigidity of the joints (rigid spine in AS is termed bamboo spin). Patients with AS may also have various complications such as uveitis.

There is no specific cure for AS. Since TNF- α , an inflammatory cytokine, is found at high levels in affected areas such as the sacroiliac joint, it is believed that neutralization of TNF- α may alleviate inflammation of affected joints.

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 monoclonal). Using the monoclonal antibody technique, manufacturers can obtain 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 body. It works by blocking tumor necrosis factor alpha (TNF- α), a protein that, when produced in excess, plays a central role in the inflammatory responses of many immune-mediated diseases. To date, HUMIRA has been approved in 80 countries and more than 370,000 people worldwide are currently being treated with it (as of August 2009). Clinical trials are also under way evaluating the potential of HUMIRA in immune diseases other than those for which the drug is currently indicated.

3. Eisai's Commitment to Immunology

Eisai, whose strength lies in low-molecular drugs, is aggressively addressing biologics. In April 2007, Eisai acquired Morphotek, Inc., a U.S. bio-venture specialized in the research and development of antibody drugs, and is now involved in the creation of antibody drugs for the

treatment of cancer, rheumatoid arthritis, and infections using Morphotek's unique technologies such as Human Morphodoma[®] and Libradoma[™]. In addition, Eisai is investigating immunotherapy for Alzheimer disease in cooperation with BioArctic Neuroscience Inc. in Sweden, and is developing and marketing Humira, a humanized anti-human TNF- α monoclonal antibody, in Japan in cooperation with Abbott Japan. Eisai is thus committed to improving the QOL of patients and their families by producing antibody drugs.

4. About Abbott

Abbott, headquartered in Chicago, IL, is a global, broad-based health care company devoted to the research and development of new drugs as well as research into, development, manufacturing, marketing, and distribution of pharmaceutical/medical products, nutritional products, medical devices, medical instruments, and diagnostics. It employs more than 72,000 people and markets its products in more than 130 countries.

In Japan, approximately 2,400 Abbott employees dedicated to the manufacturing, development, distribution, and marketing of drugs and the distribution and marketing of pharmaceutical/medical products, nutritional products, medical devices/instruments, and diagnostics. Abbott's main offices in Japan are located in Tokyo, Fukui, and Chiba.

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 immune-mediated diseases.

More information about HUMIRA, including full prescribing information, is available on the following web site: <http://www.e-humira.jp/> and www.HUMIRA.com.