

April 16, 2008

Those in the Media

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

HUMIRA® received approval for the treatment of rheumatoid arthritis in Japan

On April 16, 2008, Abbott Japan Co., Ltd. (Pharmaceutical Products Group in Osaka, President: Glenn S. Warner) and Eisai Co., Ltd. (Headquarters in Tokyo, President and CEO: Haruo Naito) announced that HUMIRA® (adalimumab), Abbott's fully-human monoclonal anti-TNF- α antibody that the companies had co-developed, received approval for manufacturing/distribution in Japan for the treatment of rheumatoid arthritis.

As the Marketing Authorization Holder for HUMIRA®, Abbott Japan will obtain approval for marketing and distribution in Japan. Eisai will use its distribution network for HUMIRA® in Japan. Also, both companies will promote HUMIRA® with a one-brand, one-channel and two-promotion scheme to provide information on the proper use of HUMIRA® via specialist medical representatives (MRs) from both companies who will coordinate with Eisai's general sales force.

HUMIRA® is the world's first fully-human 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 including rheumatoid arthritis. Since 2000, nearly 400 patients have enrolled in clinical studies of HUMIRA® in Japan in the treatment of rheumatoid arthritis and other autoimmune diseases. Following its launch, HUMIRA® will be further investigated in all-case postmarketing surveillance.

"Rheumatoid arthritis is a chronic autoimmune condition, and 600,000 to 700,000 people in Japan are suffering from this disease," said Prof. Nobuyuki Miyasaka, Department of Collagen Disease and Rheumatology, Tokyo Medical and Dental University Graduate School of Medicine, who was involved in the development of HUMIRA® for the treatment of rheumatoid arthritis in Japan. "The clinical studies of HUMIRA® in Japanese patients demonstrated the efficacy and safety of this drug. HUMIRA® is a new treatment option to prevent disease progression."

An application for approval of HUMIRA® for psoriasis is currently under review in Japan. The two companies are also developing HUMIRA® in Japan for Crohn's disease, ankylosing spondylitis, juvenile rheumatoid arthritis, and ulcerative colitis. Abbott Japan and Eisai will make every effort to improve the quality of life (QOL) of patients with intractable immunological/inflammatory diseases and their families.

[See the reference information about glossaries, and Eisai and Abbott Commitment to Immunology]

Please contact the following departments regarding this topic.

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References

1. Glossary

1) Product Name

HUMIRA® Subcutaneous injection 40mg Syringe 0.8mL

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 amino acid sequence and other characteristics.

4) Rheumatoid arthritis (RA)

Rheumatoid arthritis is an autoimmune disease in which joints are inflamed, which may lead to damage to the interior of joints and the surrounding bone. The joints most commonly affected early in the disease are the smaller joints of the fingers, feet, and wrists. The elbows, knees, ankles, and hips can also be affected. Although there is no cure for RA, people continue to seek treatments that not only alleviate the pain and inflammation but also slow disease progression, and thereby inhibit the joint damage that can hinder performance of daily activities. It is estimated that over 5 million patients in Japan, Europe and the United States, mostly between the ages of 22 and 55, are receiving antirheumatic drugs for the treatment of rheumatoid arthritis.

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. HUMIRA® is approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, and psoriasis in the United States and Europe. To date, HUMIRA® has been approved in 75 countries, and more than 250,000 people worldwide are currently being treated with HUMIRA® (as of April 2008). Clinical trials are also underway for evaluation of the potential of HUMIRA® in treating immune-mediated diseases beyond its currently approved indications.

3. Eisai's Commitment to Immunology

Eisai, which is strong in low-molecular-weight drugs, is aggressively addressing biologics. In April 2007, Eisai acquired Morphotek, Inc., a bio-venture specialized in research and development of antibody drugs in the United States, and is now involved in 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 a humanized anti-human TNF α monoclonal antibody for the treatment of immune/inflammatory diseases including rheumatoid arthritis 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. 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 and Medication Guide, is available on the Web site www.humira.com or in the United States by calling Abbott Medical Information at 1-800-633-9110 (English information only).

5. About Abbott

Abbott, headquartered in Chicago, Illinois, is a global, broad-based health care company devoted to 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 68,000 people and markets its products in more than 130 countries.

In Japan, the 2,100 people of Abbott are devoted to the manufacture, 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, Osaka, Fukui, and Chiba.

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