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

Abbott and Eisai Announce Changes in the Sales Scheme in Japan for Adalimumab, A Fully Human Monoclonal Anti-TNF-α Antibody

Eisai Co., Ltd., (Headquarters in Tokyo, President: Haruo Naito), Abbott Japan Co., Ltd., (Pharmaceutical Products Group in Osaka, President: Glenn S. Warner), and Abbott Biotechnology Ltd., (Director and President: Thomas C. Freyman) concluded changes to the sales scheme for adalimumab, a fully human monoclonal antibody on January 24. With these changes, Eisai and Abbott have finalized the basic agreement concerning co-development and marketing for adalimumab in Japan. The following changes were made:

- 1. As the Marketing Authorization Holder for the adalimumab, Abbott Japan will obtain approval for marketing and distribution in Japan. Eisai will use its distribution network for adalimumab in Japan.
- 2. Once approved, both companies will promote adalimumab, replacing the two-brand, two-channel, two-promotion scheme with a one-brand, one-channel, two-promotion scheme.
- 3. Use of HUMIRA[®], the name used in the United States and Europe, as the single trade name for adalimumab in Japan.

In Japan, adalimumab has been submitted to the Ministry of Health and Welfare for approval to treat rheumatoid arthritis and psoriasis. It is now under in Phase II/III clinical studies for the treatment of Crohn's disease. After approval, Eisai and Abbott Japan are expected to provide information on the proper use of adalimumab via specialist medical representatives (MRs) from both companies who will coordinate with Eisai's general sales force.

Adalimumab is the only fully-human monoclonal antibody for the treatment of autoimmune diseases, such as rheumatoid arthritis. Adalimumab works by neutralizing the activity of tumor necrosis factor (TNF- α), a protein that plays a central role in inflammatory reactions in patients with autoimmune diseases. To date, adalimumab has been approved in 73 countries, and more than 250,000 people worldwide are currently being treated with adalimumab. In Europe and United States, adalimumab is distributed by Abbott. The distribution agreement in Japan follows the same model currently in place in Korea and Taiwan, where Abbott and Eisai also have agreements for development and distribution.

Eisai and Abbott Japan will make every effort to release adalimumab in Japan as soon as possible to improve patients QOL with intractable immunological/inflammatory diseases including rheumatoid arthritis, psoriasis, and Crohn's disease.

[See the reference information about summarized changes in the sales scheme, glossaries, and Eisai and Abbott Commitment to Immunology]

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	Before	After
Marketing/distribution approval	Eisai and Abbott Japan will obtain approval.	Abbott will obtain approval.
Promotional activity	2-brand, 2-channel scheme	1-brand, 1-channel, 2-promotion scheme
Product name	Eisai and Abbott use different product names	Use HUMIRA [®] as the single product name in Japan
Distribution	Eisai and Abbott Japan were to distribute adalimumab separately.	Eisai will distribute adalimumab.
Specialist MRs	n/a	Eisai and Abbott Japan will establish specialist MRs

1. Summary of changes in the sales scheme for adalimumab

2. Glossary

1) TNF-a

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.

2) Monoclonal antibody

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

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 LibradomaTM. 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.

5) About Abbott

Abbott, headquartered in Chicago, Ill., 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 65,000 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 pharmaceutical/medical products, nutritional products, medical devices/instruments, and diagnostics. Abbott's main offices in Japan are located in Tokyo, Osaka, Fukui, and Chiba.