

January 29, 2008

To: Those in the Media

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

**Abbott and Eisai Finalize License Agreement in Japan for Additional Indications for Adalimumab, The Only Fully Human Monoclonal anti-TNF $\alpha$  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 a co-development license agreement for the following additional indications for adalimumab: ankylosing spondylitis, juvenile rheumatoid arthritis, and ulcerative colitis. Abbott and Eisai will cooperate in the development of these three new indications, in addition to rheumatoid arthritis and psoriasis, where applications for approval have already been submitted to the Ministry of Health and Welfare, and Crohn's disease, which is under investigation in Phase II/III studies.

Upon approval Eisai and Abbott will cooperate in marketing adalimumab in Japan under the brand name Humira<sup>®</sup> using a one-brand, one-channel, two-promotion scheme. 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.

Adalimumab is the only fully human monoclonal antibody for the treatment of autoimmune diseases, including rheumatoid arthritis. As a fully human monoclonal anti-TNF $\alpha$  antibody, adalimumab exerts effects by neutralizing the activity of tumor necrosis factor (TNF)- $\alpha$ , a protein playing a central role in inflammatory reactions in patients with autoimmune diseases. To date, adalimumab has been approved in 73 countries, and over 250,000 people worldwide are currently being treated with adalimumab.

In Europe and the United States, adalimumab is distributed exclusively by Abbott. In Korea and Taiwan, Eisai and Abbott co-promote and distribute adalimumab using a scheme similar to that in Japan.

Eisai and Abbott will make every effort to release adalimumab in Japan as soon as possible.

[See reference information under glossaries, Eisai and Abbott commitment to immunology]

Please contact the following departments regarding this topic.	
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## Reference

### 1. Glossaries

#### 1) TNF

The tumor necrosis factors (TNF's) are a group of cytokines (i.e., substances mediating cell-cell interactions) that have been found to damage tumor cells. TNFs are produced by many types of cells such as macrophages, lymphocytes, and vascular endothelial cells, and are 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 monoclonal). Antibody molecules produced using this method share identical amino acid sequences and other characteristics.

#### 3) Ankylosing spondylitis (AS)

Ankylosing spondylitis (AS) is a disease characterized by spinal stiffness. Although the causes of AS are still unclear, evidence suggests that AS is prevalent among individuals having particular types of genes. As one type of rheumatoid factor-negative spondylarthritis, AS causes inflammation of the spine, sacroiliac joints, and hip joints, as well as other sites where ligaments attach to bone, which eventually results in bony ankylosis of the spine and joints.

#### 4) Juvenile rheumatoid arthritis (JRA)

Juvenile rheumatoid arthritis (JRA) is defined as chronic arthritis beginning before age 16 years of age, and is clinically classified as a subtype of rheumatoid arthritis. JRA is often associated with rash, pericarditis, splenohepatomegaly, lymphadenopathy, and uveitis. Despite its name, JRA often differs in disease characteristics from rheumatoid arthritis in adult patients. However, both JRA and rheumatoid arthritis in adults may cause destruction of joint surfaces and joint contracture.

#### 5) Ulcerative colitis (UC)

Ulcerative colitis (UC) is an inflammatory disease of the colon that causes erosion and ulceration of the mucosa that lines the inner surface of the colon. UC is characterized by diarrhea (with melena in many cases) and abdominal pain. Ulcer and erosive lesions often develop in the rectum first and then spread upward to the other parts of the colon, and in severe cases to the entire colon. The causes of UC are unknown. UC, together with Crohn's disease, belongs to a group of intestinal disorders called inflammatory bowel disease.

## **2. Eisai's Commitment to Immunology**

Eisai's strength has been in low-molecular-weight drugs but is currently addressing biologics aggressively. In April 2007 Eisai acquired Morphotek, Inc., a bio-venture specializing in research and development of antibody drugs in the United States, 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<sup>®</sup> and Libradoma<sup>™</sup>. 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 $\alpha$  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.

## **3. 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.

## **4. 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 2100 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.