

September 30<sup>th</sup>, 2009

For Press

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

**(Adalimumab), a Fully**

**Human Monoclonal Anti-TNF- $\alpha$  Antibody, for the Treatment of Crohn's Disease  
in Japan**

Abbott Japan Co., Ltd. (Pharmaceutical Products Group, Headquarters: Tokyo, President: Glenn S. Warner, "Abbott Japan") and Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, "Eisai") announced today that they had submitted an application for approval of Crohn's disease as an additional indication for Humira<sup>®</sup> (adalimumab), a fully human monoclonal anti-TNF- $\alpha$  antibody jointly developed by the two companies.

If approved, Crohn's disease will be the third indication for Humira, following rheumatoid arthritis (approved in April 2008) and psoriasis vulgaris and psoriatic arthritis (currently under review for approval).

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

In the two placebo-controlled, double-blind comparative studies of Humira in patients with moderate or severe Crohn's disease performed in Japan to evaluate its efficacy in inducing and maintaining remission, Humira demonstrated excellent efficacy equivalent to that observed in foreign studies.

Crohn's disease is characterized by recurrent ulcers and inflammation in the gastrointestinal tract, and the number of patients with it is increasing. By providing Humira as a new treatment option for Crohn's disease, Abbott and Eisai will contribute to improving the quality of life (QOL) of patients.

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## **1. Glossary**

### **1) Crohn's disease**

Crohn's disease is a chronic autoimmune disease of unknown etiology that is characterized by inflammatory lesions mainly in the small and large intestine. The Ministry of Health, Labor, and Welfare has designated Crohn's disease as a specified disease for which financial support is provided for healthcare. Crohn's disease has become increasingly common during the last 10 years. As at the end of 2007, about 27,000 patients were registered (data from the Japan Intractable Disease Information Center).

Crohn's disease is more prevalent among males, with a male/female ratio of 2:1, and its most common age of onset is 20~29 years. Crohn's disease is characterized by intestinal stenosis, ileus, intestinal abscesses (collections of pus resulting from infection) and perianal fistulas (ulcers in the intestine that form tunnels to surrounding intestinal wall or skin). When signs and symptoms cannot be controlled with drug therapy, patients may require surgical treatment. Since patients with Crohn's disease often exhibit flare-ups and periods of remission, long-term treatment is required to prevent recrudescence (recurrence of gastrointestinal inflammation) and recurrence (occurrence of inflammation in a new region) even after achieving remission.

### **2) TNF- $\alpha$**

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-

Neuroscience Inc. in Sweden, and is developing and marketing a humanized anti-human TNF- $\alpha$  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 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. The company employs more than 68,000 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](http://www.HUMIRA.com).