September 25, 2007

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

Abbott and Eisai submit application for adalimumab, the only fully human monoclonal anti-TNFα antibody, to treat psoriasis

Abbott Japan Co., Ltd. (Pharma Products Group in Osaka, President: Glenn S. Warner,) and Eisai Co., Ltd. (Headquarters in Tokyo, President and CEO: Haruo Naito) submitted an application for approval to manufacture and distribute adalimumab (development code: D2E7) as a drug for the treatment of psoriasis vulgaris and psoriatic arthritis on September 20. This is the second indication application for adalimumab in Japan, following an application to treat rheumatoid arthritis submitted in December 2005. Adalimumab was jointly developed by Abbott and Eisai in Japan.

Adalimumab is a fully human monoclonal antibody that works by neutralizing TNF α, a protein that plays a central role in inflammatory responses in autoimmune diseases.

In a clinical study conducted in Japan on 169 psoriasis patients, adalimumab significantly improved skin symptoms and quality of life (QOL) in patients with moderate to severe psoriasis compared to placebo and was well tolerated. The results of the study were presented at the 22nd Annual Meeting of the Japanese Society for Psoriasis Research held on September 7 and 8, 2007.

In March 2007, Abbott filed supplemental applications for the use of adalimumab for patients with moderate and severe psoriasis to the Food and Drug Administration (FDA) in the US and the European Medicines Evaluation Agency (EMEA).

In Japan, there are an estimated 100,000 patients with psoriasis. Eisai and Abbott Japan are making every effort to obtain early approval for the drug in order to improve the QOL of patients with psoriasis.

Please contact the following departments regarding this topic.	
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1. Clinical studies of adalimumab in psoriasis

The submission is based on the results from three double-blind, placebo-controlled clinical trials of adalimumab. In each trial, reduction in disease activity was determined by the Psoriasis Area and Severity Index (PASI) score, which measures the extent and severity of psoriasis.

1) REVEAL Study

REVEAL was conducted in the U.S. and Canada. It is a 52-week trial in which the short-term and sustained clinical efficacy and safety of adalimumab were evaluated in 1,200 patients with moderate to severe chronic plaque psoriasis. The percentages of patients achieving PASI 75 (75 percent or greater improvement of PASI) were 71 percent and 6.5 percent among those receiving adalimumab and a placebo, respectively, with a significant difference between the two groups. 20 percent of patients receiving adalimumab achieved PASI 100 (complete clearance of signs/symptoms of psoriasis), compared to less than 1 percent of patients receiving placebo.

2) CHAMPION Study

The CHAMPION study was conducted in 8 European countries and Canada. It is a 16-week study evaluating 271 psoriasis patients with moderate to severe chronic plaque psoriasis to compare the efficacy of adalimumab and methotrexate, a standard treatment for psoriasis in the U.S. and Europe. The percentages of patients who achieved PASI 75 at week 16 of treatment were 80 percent, 36 percent, and 19 percent in the adalimumab, methotrexate, and placebo groups, respectively, with a significant difference between the adalimumab and methotrexate groups. 17 percent of patients treated with adalimumab achieved PASI 100 at week 16, compared to 7 percent of patients receiving methotrexate and 2 percent of patients receiving placebo. In addition, a mean PASI improvement of 57 percent was achieved at week 4 in patients receiving adalimumab, compared to baseline.

3) Clinical study of psoriasis in Japan

A 24-week double-blind clinical study comparing three doses of adalimumab and placebo in a total of 169 patients with moderate to severe psoriasis (including patients with joint symptoms consistent with psoriatic arthritis) was conducted at 42 institutions in Japan (primary efficacy evaluation lasted for 16 weeks).

The percentages of patients achieving PASI 75 at week 16 were 57.9 percent, 62.8 percent, and 81.0 percent in patients receiving adalimumab at 40 mg every 2 weeks, 40 mg every 2 weeks plus an 80 mg loading dose at the first administration, and 80 mg every 2 weeks, respectively, and was significantly higher in the adalimumab groups than in the placebo group (4.3 percent). The percentage of patients with PASI 75 among those receiving adalimumab was significantly

higher at week 4 and thereafter, indicating rapid onset of efficacy. Evaluation of QOL using DLQI and SF36 revealed that adalimumab was superior to placebo in improving the QOL of psoriasis patients. No clinically significant difference between adalimumab and placebo was observed in terms of safety. The safety profile of adalimumab in psoriatic patients was similar to that had been observed in the study previously conducted with rheumatoid arthritis patients.

*PASI: The Psoriasis Area and Severity Index (PASI) is an overall measure of the severity and extent of dermal signs/symptoms of psoriasis that is commonly used to evaluate the efficacy of treatment.
*DLQI: The Dermatology Life Quality Index (DLQI) is a measure of the quality of life (QOL) of patients with dermal disease.
*SF 36: The MOS Short Form 36-item Health Survey (SF36) is a measure of health-related quality of life that consists of 36 questions.

2. Glossaries

1) Psoriasis

Psoriasis is a non-contagious, often painful autoimmune disease characterized by raised, inflamed, scaly, red skin lesions known as plaques, which may crack and bleed. In addition to these visible symptoms, patients with psoriasis may suffer from poor self-image and social isolation, possibly resulting in deterioration of personal relationships in the workplace and community.

Patients with psoriasis may suffer from raised red skin lesions covered with silvery scales that may be painful and feel hot. Psoriasis often affects the scalp, knees, elbows, back and extremities, but may also affect other skin areas, nails, and joints.

While psoriasis can occur in people of all ages, it typically appears in patients between the ages of 15 and 35. The severity of psoriasis differs among individuals. Although patients with mild psoriasis mainly undergo topical treatment while those with severe psoriasis undergo systemic treatment and phototherapy, there is currently no cure for psoriasis.

2) TNFα

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 such as 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 monoclones). Using the monoclonal antibody technique, we can obtain a homologous population of antibody molecules identical in amino acid sequence and other characteristics.

3. About Abbott

Abbott, headquartered in Chicago, Ill., is a global, broad-based heath 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 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 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.

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 adalimumab (foreign trade name: HUMIRA®), including full prescribing information, is available on the web site www.HUMIRA.com or in the United States by calling Abbott Medical Information at 1-800-633-9110.