

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

Fully Human Monoclonal Anti-TNF- α Antibody HUMIRA[®] Receives Approval as Japan's First Biological Agent for Psoriasis

Abbott Japan Co., Ltd. (Pharmaceutical Products Group Headquarters: Tokyo, President: Gary M. Winer, "Abbott Japan") and Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, "Eisai") today announced that HUMIRA[®] pre-filled syringe 40 mg/0.8 mL for subcutaneous injection (generic name: adalimumab) has received approval for the additional indications of plaque psoriasis (PS) and psoriatic arthritis (PSA). HUMIRA[®] is a fully human anti-TNF- α monoclonal antibody jointly developed by the two companies in Japan. This approval marks the second indication approved for HUMIRA[®] in Japan following rheumatoid arthritis, which was approved in April 2008. HUMIRA[®] will be the first biological agent approved for the treatment of psoriasis in Japan.

HUMIRA[®] is a fully human anti-TNF- α monoclonal antibody that exerts its effects by neutralising TNF α , a cytokine that plays a central role in inflammatory responses. While Abbott Japan is the marketing authorisation holder of HUMIRA[®] in Japan and Eisai is responsible for distributing the drug, the two companies have been co-promoting the drug. Post-marketing observation survey (PMOS) will be conducted in all patients treated with the drug over a given period of time in order to promote its effective and safe use in treating psoriasis.

In the clinical study conducted in 169 patients with moderate or severe PS in Japan, patients treated with HUMIRA[®] showed significant improvement in skin symptoms and QOL (quality of life) compared to those with placebo, indicating that the drug has a favourable tolerability profile.

Psoriasis is a chronic, non-communicable, inflammatory disease that is thought to involve interaction between inflammatory and skin cells. The number of patients with the disease in Japan is estimated to be approximately 100,000. Abbott Japan and Eisai will work in tandem to provide HUMIRA[®] as a new treatment for PS, which is considered to be the most common type of psoriasis, and PSA which is associated with progressive joint symptoms, thereby making contributions to improving the QOL of patients.

[Please refer to the following notes for product information, clinical trial outline, a glossary of terms, and an overview of Abbott and Eisai's Commitment to Immunology]

Contacts:	
Public Relations Department Eisai Co., Ltd. Tel: +81-3-3817-5120	Public Affairs Department Abbott Japan Co., Ltd. Tel: +81-3-4588-4602

1. HUMIRA® Pre-Filled Syringe 40 mg/0.8 mL for Subcutaneous Injection (Underlined parts indicate new indications)

1) Indications

HUMIRA® is indicated for treatment of patients with the following diseases not responding to conventional treatment:

- Rheumatoid arthritis
- Plaque Psoriasis, psoriatic arthritis

2) Dosage and Administration

HUMIRA® is administered by subcutaneous injection.

[Rheumatoid arthritis]

For adult patients, 40 mg of adalimumab (recombinant) every other week. If the effect of the treatment proves inadequate, the dose may be increased to 80 mg.

[Psoriasis vulgaris and psoriatic arthritis]

For adult patients, an initial dose of 80 mg of adalimumab (recombinant), followed by 40mg every other week. If the effect of the treatment proves inadequate, the dose may be increased to 80 mg.

2. About HUMIRA® Psoriasis Clinical Studies

Four main clinical trials were conducted for HUMIRA® in psoriasis. In each clinical trial, cutaneous disease activity was primarily determined by the Psoriasis Area and Severity Index (PASI) score.

1) Psoriasis Clinical Study in Japan

The study was a 24-week, double-blind, placebo-controlled clinical trial in 169 patients with moderate to severe psoriasis, including patients with psoriatic arthritis with joint symptoms, conducted at 42 centres across Japan, which compared three different dosages of adalimumab against placebo (primary efficacy was evaluated up until Week 16). The percentages of patients achieving PASI 75 (75 percent or greater improvement of PASI) at week 16 were 57.9 %, 62.8 %, and 81.0 % in patients receiving adalimumab at 40 mg every other week, 40 mg every other week plus a 80 mg loading dose at the initial administration, and 80 mg every other week, respectively, with a significantly higher number of patients treated with adalimumab experiencing improvement compared to the placebo group (4.3 percent). The percentage of patients with PASI 75 among those treated with adalimumab was significantly higher at Week 4 and thereafter, indicating rapid onset of efficacy. Evaluation of QOL* using DLQI* and SF36* showed significant improvement of the QOL in patients treated with adalimumab compared to those with placebo. The safety profile of adalimumab of this study was consistent with that seen in studies in patients with rheumatoid arthritis.

2) REVEAL Study

REVEAL was a 52-week study to evaluate the short-term and long-term efficacy and safety of adalimumab in 1,212 patients with moderate to severe chronic plaque psoriasis in the U.S. and Canada.

PASI 75 at Week 16 was 71 % in patients treated with adalimumab and 7 % in those with placebo, respectively. Patients with adalimumab showed significant improvement compared to the placebo. PASI 100 (complete disappearance of cutaneous symptoms) at Week 16 was observed in 20 % of patients treated with adalimumab compared to 1 % of those with placebo.

3) CHAMPION Study

This is a 16-week study to compare the efficacy of adalimumab and methotrexate, a standard treatment for psoriasis in the U.S. and Europe, in 271 patients with moderate to severe psoriasis in eight European countries and Canada.

PASI 75 at Week 16 was 80 %, 36 %, and 19 %, in the adalimumab, methotrexate, and placebo groups, respectively. Adalimumab-treated patients showed significant improvement compared to methotrexate-treated patients. PASI 100 at Week 16 was seen in 17 % of patients treated with adalimumab compared to 7 % of those with methotrexate and 2 % of those with placebo. In addition, a mean PASI improvement at Week 4 was 57 % in patients receiving adalimumab.

4) ADEPT Study

The ADEPT Study was conducted in 313 patients with psoriatic arthritis in the U.S., Canada, and six European countries to evaluate the efficacy and safety of adalimumab in psoriatic arthritis.

ACR 20 at Week 12 was 58 % in patients treated with adalimumab compared to 14 % in those with placebo, with significant improvement in favour of those with adalimumab. The change in the modified Total Sharp Score, a measure of joint destruction, from the baseline at Week 24 was significantly smaller in patients with adalimumab than that in those with placebo, indicating that adalimumab prevented the progression of joint destruction in patients with psoriatic arthritis.

*PASI: The Psoriasis Area and Severity Index (PASI) is an overall measure of the severity and extent of cutaneous 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 cutaneous 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.

3. Glossary

1) Psoriasis

Psoriasis is a chronic inflammatory disease that is thought to involve interaction between inflammatory and skin cells. It is characterised by raised, inflamed, scaly red lesions called “plaques”.

In plaque psoriasis, the most common type of psoriasis, raised patches of erythema appear on parts of the body, and the skin in that area is often covered with silvery white scales that cause an itching or burning sensation. While the most frequently affected areas include the scalp, knees, elbows, buttocks, and limbs, the disease may occur on other parts of body, such as the skin, finger or toe nails, and joints. Psoriasis can be broadly divided into five clinical subtypes, including plaque psoriasis, which is said to occur more frequently than other types, and psoriatic arthritis which is associated with progressive and inflammatory joint symptoms.

Psoriasis appears in people of all ages, from individuals in their teens through to elderly people in their seventies or older, however, it most commonly occurs in patients in their fifties. The severity of signs/symptoms of psoriasis differs among individuals. Although topical treatments are used for patients with mild psoriasis, systemic treatment and phototherapy are used to treat moderate to severe patients.

2) TNF α

The tumour necrosis factors (TNFs) are a group of cytokines (i.e., substances mediating cell-cell interactions) mediating intercellular communication that have been found to damage tumour 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. TNF- α , when produced in excess, plays a central role in the inflammatory responses of some immune-mediated diseases.

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 affinity and specificity to the target antigen.

4. About HUMIRA[®]

HUMIRA[®] resembles antibodies normally found in the body. It works by blocking tumour necrosis factor alpha (TNF- α), a cytokine that plays a central role in inflammatory responses. To date, HUMIRA[®] has been approved in 82 countries and more than 420,000 people (as of January 2010) worldwide are currently being treated with HUMIRA[®]. HUMIRA[®] has been extensively studied and has a large safety database across multiple indications in more than 19,000 patients over 12 years. Several clinical trials are also under way to evaluate the potential of HUMIRA[®] in treating immune-mediated diseases other than those for which the drug is currently indicated.

5. Eisai's Commitment to Immunology

Eisai, whose strength lies in low-molecular-weight drugs, is aggressively addressing biologics. In April 2007, Eisai acquired Morphotek, Inc., a U.S. bio-venture specialized in the research and development of antibody drugs, and is now involved in the creation of antibody drugs for the treatment of cancer, rheumatoid arthritis, and infectious diseases using Morphotek's proprietary 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 HUMIRA[®], a fully human monoclonal anti-TNF α 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.

6. About Abbott

Abbott 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 more than 72,000 people and markets its products in more than 130 countries.

In Japan, the 2,000 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, Fukui, and Chiba. Press releases issued by Abbott Japan and Abbott Headquarters can be viewed at www.abbott.co.jp and www.abbott.com, respectively.

7. 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 websites: <http://www.e-humira.jp/> and www.HUMIRA.com.