AbbVie GK Eisai Co., Ltd.

# AbbVie and Eisai Announce HUMIRA® Pre-filled Syringe Has Received Approval for the Treatment of Intestinal Behçet's Disease in Japan

HUMIRA is the First Biologic Approved to Treat Intestinal Behçet's Disease in Japan

AbbVie GK (Headquarters: Tokyo, President: Gary M. Winer, %bbVie+) and Eisai Co., Ltd. (Headquarters: Tokyo, President and CEO: Haruo Naito, %bisai+) today announced that they have received indication approval for the treatment of intestinal Behçets disease for HUMIRA® Pre-filled Syringe 40 mg / 0.8

1. HUMIRA® Pre-

Program. BD develops in males and females in their late 20s to 40s, who are in their most productive years. Although the etiology of BD is still unknown, involvement of specific genetic factors is suspected since the prevalence of HLA-B51, a major histocompatibility complex class I antigen, is high among patients with BD. Patients with BD may experience intestinal symptoms such as abdominal pain, abdominal discomfort, and diarrhea, and may have ulcers in the ileocecum, which is located in the right lower abdomen, in addition to the above-mentioned four main clinical findings. BD associated with intestinal signs/symptoms is referred to as intestinal BD. When intestinal ulcers are worsened, intestinal bleeding and perforation may develop and require urgent surgery.

#### 2) TNF-

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- 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.

#### 3) Monoclonal antibody

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

#### 3. About HUMIRA®

HUMIRA® has been approved in Japan for rheumatoid arthritis (April 2008), plaque psoriasis and psoriatic arthritis (Pa) \* & ÁGEFETÃÔ![ @ q Áåã^æ^ÁÇJ&{ à^!ÁGEFETÃÀ; \^ |[• ¾ \* Á•][ } å | ãã ÁÇJ&{ à^!ÁGEFETÃÖ ç^} ¾ Á idiopathic arthritis (July 2011), and intestinal Behç^æ Áãã^æ ÁÇT æ ÁG€13). And "including inhibition of structural damage" was added to the indication of "rheumatoid arthritis" on August 2012.

#### 4. AbbVie's commitment to immunology

AbbVie is focused on the discovery and development of innovative treatments for immunologic diseases. The Abbott Bioresearch Center, founded in 1989 in Worcester, Mass., the United States, is a world-class discovery and basic research facility committed to finding new treatments for autoimmune diseases.

More information about HUMIRA®, including full prescribing information, is available on the Web sites <a href="http://www.e-HUMIRA.ip">http://www.e-HUMIRA.ip</a> (Japanese only) and <a href="http://www.e-HUMIRA.ip">www.HUMIRA.ip</a> (Japanese only) and <a href="http://www.e-HUMIRA.ip">www.e-HUMIRA.ip</a> (Japanese only) and <a href="http://www.e-HUMIRA.ip">www.e-HUMIRA.ip</a> (Japanese only) and <a href="http://www.e-HUMIRA.ip">http://www.e-HUMIRA.ip</a> (Japanese o

### 5. Eisai's commitment to immunology

## 6. About AbbVie