

**EISAI PRESENTS LATEST PHASE I/II DATA ON
IN-HOUSE DEVELOPED ANTI-FRACTALKINE ANTIBODY E6011**
*RESULTS SUGGEST SAFETY, TOLERABILITY AS WELL AS CLINICAL ACTIVITY
IN RHEUMATOID ARTHRITIS AND CROHN'S DISEASE*

Eisai Co., Ltd. (Headquarters: Tokyo, Japan) announced interim analyses on the latest data for anti-fractalkine monoclonal antibody E6011, discovered by Eisai research subsidiary KAN Research Institute Inc. (Headquarters: Hyogo, President and Representative Director: Toshio Imai), from

[Notes to editors]

1. About E6011

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4) patient's assessment of function, 5) physician's global assessment of disease status, 6) patient's global assessment of disease status and 7) acute-phase reaction protein [CRP or ESR] levels), ACR20 response is the proportion of patients who achieve at least a 20% improvement in 1) and 2) and a 20% improvement in at least three of the five criteria from 3) to 7). Similarly ACR50 and ACR70 are the proportion of patients who achieve at least a 50% improvement and 70% improvement in the criteria, respectively.

4. About 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 recent years. As at the end of fiscal 2013, 39,799 patients were registered in Japan. The prevalence of Crohn's disease is higher in the United States and Europe, it is estimated that there are approximately 200 patients per 100,000 people in the United States compared to approximately 27 patients per 100,000 people in Japan.⁵

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.

5. About Rheumatoid Arthritis

Rheumatoid arthritis is a disease that leads to the inflammation of multiple joints throughout the body, causing joint swelling and pain. With joint destruction progressing right from the early stages of the disease, rheumatoid arthritis causes joint deformities and functional impairment over the long term. Rheumatoid arthritis is an autoimmune disease in which synovial cells, which line the inner surface of the joint cavity, proliferate due to an unknown cause. The number of blood vessels in joints also increases, resulting in the migration of lymphocytes, macrophages and other white blood cells from inside blood vessels to the synovial tissue of joints. An immune reaction in localized joints causes an inflammatory reaction and the progression of cartilage and bone destruction due to the effects of cytokines produced by lymphocytes and macrophages. The global prevalence of rheumatoid arthritis varies between 0.3% and 1%.⁶ In Japan, rheumatoid arthritis is said to affect an estimated 700,000 to 800,000 patients.

¹ Matsuoka K, et al., Safety, Tolerability and Efficacy of E6011, Anti-Human Fractalkine Monoclonal Antibody, in the First-Patient Study. *Journal of Gastroenterology and Hepatology* 2016, Poster Number Mo1890.

² Tanaka Y, et al., Safety and Efficacy of E6011, an Anti-Fractalkine Monoclonal Antibody, in a First-in-Patient Phase 1/2 Study in Rheumatoid Arthritis. *ACR 2015*. Late-breaking Abstract Number 13L

³ Tanaka Y, et al., Safety, *Pharma*, 4, 1127–1131 (2015)