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FOR IMMEDIATE RELEASE

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

Abbott Japan and Eisai Receive Approval in Japan for Additional Indication and New Formulation of Humira®, a Fully Human Anti-TNF-α Monoclonal Antibody, for the Treatment of Juvenile Idiopathic Arthritis

Abbott Japan Co., Ltd. (Pharmaceutical Products Group Headquarters: Tokyo, President & CEO: Gary M. Winer, "Abbott Japan") and Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that they have received approval from Japan's Ministry of Health, Labour, and Welfare (MHLW) for polyarticular juvenile idiopathic arthritis (JIA) as an additional indication of Humira® (adalimumab) Pre-filled Syringe 40 mg/0.8 mL for Subcutaneous Injection, a fully human anti-TNF-α monoclonal antibody jointly developed by the two companies in Japan.

In addition to the new indication, Humira® Pre-filled Syringe 20 mg/0.4 mL for Subcutaneous Injection, a new formulation for patients with a low body weight, also received approval from the MHLW. Abbott Japan and Eisai plan to launch the new formulation in Japan upon completion of drug price-listing registration.

Humira® is a fully human anti-TNF-α monoclonal antibody that exerts its effects by neutralizing TNF-α, a cytokine that plays a central role in inflammatory responses. In Japan, Abbott Japan is the marketing and manufacturing authorization holder for Humira®, while Eisai is responsible for its distribution. The two companies are working together to promote the product under a one-brand, one-channel, two-promotion scheme.

JIA is a chronic disease defined as arthritis of unknown etiology that manifests itself before the age of 16 years and persists for at least 6 weeks. It is estimated to affect 8.79 out of every 100,000 children. The disease often causes significant disadvantages to school age patients as the need for frequent hospital visits interferes with their academic performance, which can ultimately become an obstacle in planning for future education or employment.

In a clinical study conducted in Japan of Humira® given alone and in combination with methotrexate in 25 polyarticular JIA patients with disease activity inadequately controlled by conventional therapies, Humira® demonstrated symptomatic improvements consistent with those observed in an overseas trial and was well-tolerated.

By providing Humira® as a new treatment option for JIA, Abbott and Eisai seek to make contributions to improve the quality of life (QOL) of patients.

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