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FOR IMMEDIATE RELEASE

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

Abbott Japan and Eisai Submit Application in Japan for Additional Indication of Humira® (adalimumab), a Fully Human Anti-TNF-α Monoclonal Antibody, for Inhibition of Structural Damage of Joints in Rheumatoid 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 submitted an application in Japan seeking approval of inhibition of structural damage of joints in rheumatoid arthritis as an additional indication for Humira® (adalimumab; recombinant) Pre-filled Syringe 40 mg/0.8 mL, a fully human anti-TNF-α monoclonal antibody jointly developed by the two companies.

The submission is based on the results of a double-blind study (HOPEFUL1 Study) conducted to satisfy the post-approval commitment that was imposed on April 16, 2008 when rheumatoid arthritis was approved as an additional indication for Humira®. The post-approval commitment required that a long-term (at least one year) double-blind clinical study comparing Humira® with an appropriate control drug must be carried out in order to confirm the drug's efficacy (including efficacy in inhibiting the progression of joint destruction) and safety.

The HOPEFUL1 Study involved 334 rheumatoid arthritis patients of less than two years duration who have received no prior treatment with methotrexate ("MTX"), a first-line therapy for the disease. In the study, patients received concomitant treatment using either Humira® with MTX or placebo with MTX. An analysis conducted at Week 26 showed that Humira® with MTX had a statistically significant inhibitory effect on the progression of joint destruction compared to MTX alone in the study's primary endpoint of modified Total Sharp Score (a measure of joint destruction). Furthermore, in addition to showing that Humira® with MTX was significantly superior in improving clinical symptoms and physical function, the study also demonstrated that the incidence of adverse events was consistent with other clinical studies conducted with Humira®, and that the drug was well-tolerated in combination with MTX. The results of the study were presented on September 17, 2011 at the 39th Annual Meeting of The Japan Society of Clinical Immunology.

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.

Abbott Japan and Eisai remain committed to expanding the range of indications for which Humira® is approved as they seek to address unmet medical needs and improve the quality of life (QOL) of patients.

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