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

Abbott Japan and Eisai Announce Launch of Humira® Prefilled Syringe 20mg/0.4mL, a New Formulation for the Treatment of Juvenile Idiopathic Arthritis in Patients with Low Body Weight

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 will launch Humira[®] (adalimumab) Prefilled Syringe 20mg/0.4mL, a fully human anti-TNF-α monoclonal antibody for the treatment of polyarticular juvenile idiopathic arthritis (JIA) patients with low body weight, on September 29.

Humira[®] Prefilled Syringe 20mg/0.4mL received manufacturing and marketing approval from Japan's Ministry of Health, Labour and Welfare on July 1 of this year and was subsequently listed on the National Health Insurance (NHI) Price List on September 12.

The new 20mg prefilled syringe is a new formulation of Humira[®] that was developed as a treatment for JIA patients with a body weight of between 15kg and 30kg. While it is possible to administer Humira[®] Prefilled Syringe 40mg/0.8mL in divided doses according to a patient's weight, a characteristic feature of the new formulation is that it can be self-administered easily as a subcutaneous formulation that can be used up entirely in a single dose.

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.

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.

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.

*FY2000 Health Sciences Research Grant (Research on Children and Families)-Supported Research Report, Field Study on Juvenile Rheumatoid Arthritis and Medical Administrative Policy Making for QOL Improvement

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