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Singapore: Japanese pharmaceutical companies AbbVie GK, Eisai Co Ltd and its subsidiary EA Pharma Co Ltd have announced that they have received additional approval for a new dosing regimen of Humira Pre-filled Syringe 40 mg/0.8 mL for Subcutaneous Injection (generic name: adalimumab[recombinant], Humira), a fully human anti-TNF monoclonal antibody formulation, in patients with moderate or severe Crohn's disease who become less responsive to treatment with 40 mg every two weeks to double the dose to 80 mg every two weeks.

The usual adult dose of Humira for Crohn's disease is initial dose of 160 mg of adalimumab (recombinant) given subcutaneously (SC) followed by 80 mg SC two weeks after the initial dose, then after four weeks of the initial dose. Thereafter, 40 mg SC is given every two weeks. However, some patients became less responsive during their course of treatment, necessitating therapy aimed at 'long-term maintenance of remission' which is the goal of treatment for Crohn's disease.

Recently, a Japanese clinical study demonstrated the efficacy of an increased dose of 80 mg every two weeks in patients who become less responsive to the conventional dose. As a result, an additional approval was granted for a change in dosing regimen for these patients.

The Japanese Clinical Study on which the present approval was granted was conducted at 12 trial sites with 28 patients suffering from moderate or severe Crohn's disease who became less responsive to treatment with 40 mg every two weeks.

In Japan, AbbVie is the marketing and manufacturing authorization holder for Humira. For the indications in the field of gastrointestinal disease (i.e., ulcerative colitis, Crohn's disease, and intestinal Bechet's disease), AbbVie and EA Pharma, a subsidiary of Eisai, are co-promoting Humira. Abbvie and Eisai are co-promoting Humira for the indications in the fields other than gastrointestinal disease (i.e. rheumatoid arthritis, plaque psoriasis, arthropathic psoriasis, ankylosing spondylitis, and juvenile idiopathic arthritis).

AbbVie, Eisai and EA Pharma will continue to promote and provide information on the proper use of HUMIRA while making further contributions to improve the quality of life of patients.