

Eisai receives approval for an additional indication of HUMIRA

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AbbVie and Eisai have announced that they have received approval for an additional indication of HUMIRA®, a fully human anti-TNF- α monoclonal antibody for the treatment of hidradenitis suppurativa (HS).

With this approval, HUMIRA has become the first treatment indicated for HS in Japan, and is now approved for 11 indications in Japan.

The approval of this additional indication is based on the data from a Japanese Phase III study and overseas clinical trials. In these trials, the efficacy and safety of HUMIRA were evaluated in patients with moderate to severe HS.

HS is a painful, inflammatory skin disease with a chronic course which typically presents after puberty. Inflammatory symptoms are frequently observed in the axillary, inguinal, breast-fold, and gluteal regions. The main symptom is red, swollen boil-like lumps, and the progression of symptoms leads to formation of nodules, abscesses, and even fistulas. Repeated recurrence causes thickening of the affected areas, resulting in scarring.

Dr. Tadashi Terui, Professor, Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine said, "This approval will be a major step for patients with HS. HS is a recurrent disease with pain and pus discharge. It has a significant impact on patients quality of life, affecting their work or study performance and, in advanced cases, requiring major surgery with skin grafting. Only limited options have been available for the treatment of HS until now. The additional indication of HUMIRA for HS is expected to significantly contribute to the improvement in patients' quality of life."

AbbVie and Eisai will continue to promote and provide information on the proper use of HUMIRA®