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Japan first in world to approve Dupixent for chronic spontaneous urticaria

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Chronic spontaneous urticaria is the fifth approved indication for Dupixent in Japan and the sixth indication for Dupixent globally



The Ministry of Health, Labour and Welfare (MHLW) in Japan has granted marketing and manufacturing authorisation for Dupixent (dupilumab) for the treatment of chronic spontaneous urticaria (CSU) in people aged 12 years and older whose disease is not adequately controlled with existing therapy. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

Japan is the first country to approve Dupixent for CSU, emphasising the value of Dupixent as a novel treatment option to manage this disease in patients with unmet needs.

CSU is a chronic inflammatory skin disease driven in part by type 2 inflammation, which causes sudden and debilitating hives and persistent itch. CSU is typically treated with histamine (H1) antihistamines, medicines that target H1 receptors on cells to control symptoms of urticaria. However, the disease remains uncontrolled despite antihistamine treatment in many patients, some of whom are left with limited alternative treatment options.

Approximately 110,000 people aged 12 years and older suffer from uncontrolled moderate-to-severe CSU in Japan, for which there are currently limited treatments.

In addition to CSU, Dupixent is approved in Japan in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), and prurigo nodularis.