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Japan approves manufacturing and marketing of Adtralza for atopic dermatitis treatment

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Adtralza to be administered as a subcutaneous injection in adults



Denmark-based LEO Pharma A/S, a global leader in medical dermatology, has announced that the Japan Ministry of Health, Labor and Welfare (MHLW) has granted approval for the manufacturing and marketing of Adtralza® (tralokinumab) subcutaneous injection for adults with atopic dermatitis, which has inadequately responded to conventional therapies.

Atopic dermatitis is a chronic, inflammatory, skin disease characterized by intense itch and eczematous lesions. Atopic dermatitis is the result of skin barrier dysfunction and immune dysregulation, leading to chronic inflammation

Adtralza is the first and only approved human, monoclonal antibody developed to specifically target and neutralise the IL-13 cytokine, which plays a key role in the immune and inflammatory process which are the underlying causes of atopic dermatitis signs and symptoms. The MHLW has approved Adtralza to be administered as a subcutaneous injection in adults with an initial dose of 600mg, followed by a 300mg dose given every other week.

The approval is based on results from the global pivotal trials ECZTRA 1, 2, and 3,the Japanese pivotal trial ECZTRA 8, and the global open-label extension trial ECZTEND.