

Australia approves new therapy for children with growth hormone deficiency

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SKYTROFA® (lonapegsomatropin) is now registered by the Therapeutic Goods Administration



Singapore-based biopharmaceutical company Specialised Therapeutics (ST) has announced the Australian registration of SKYTROFA® (lonapegsomatropin) as a new once-weekly injectable therapy for paediatric growth hormone deficiency (GHD).

The Therapeutic Goods Administration (TGA) has approved SKYTROFA as a treatment for "growth failure in children and adolescents aged from 3 years up to 18 years due to insufficient endogenous growth hormone secretion".

GHD is a rare disease affecting around 2-3/10,000 Australians, with approximately 2,000 children thought to be living with the condition. The goal of treatment for GHD is to restore normal levels of growth hormone in the body, reduce physical symptoms, enhance metabolic health and improve quality of life.

ST Chief Executive Officer, Carlo Montagner, said the TGA approval of SKYTROFA demonstrated the company's ongoing mission to support patients with rare diseases in Australia and the Asia-Pacific region.

SKYTROFA is being registered in Australia by ST, under an exclusive distribution agreement with biopharmaceutical company Ascendis Pharma A/S that covers Australia, New Zealand, Singapore, Malaysia, Brunei, Thailand, and Vietnam.

The Australian registration of SKYTROFA follows approvals issued to Ascendis Pharma by the United States Food and Drug Administration (US FDA) in August 2021 and the European Medicines Agency (EMA) in January 2022.

Developed using Ascendis Pharma's proprietary TransCon™ platform, SKYTROFA is delivered as a subcutaneous injection, available in various strengths. The starting dose depends on the patient's body weight and is then adjusted individually by the treating endocrinologist based on the patient's response to treatment.

SKYTROFA is a prodrug of somatropin administered once weekly, designed to provide sustained release of active, unmodified somatropin. This allows the medicine to slowly release unmodified growth hormone into the body over the course

of one week, removing the need for daily injections.