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Australia approves first and only treatment for chronic hypoparathyroidism

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YORVIPATH (palopegteriparatide) is now registered by the Therapeutic Goods Administration (TGA) for the treatment of chronic hypoparathyroidism in adult

Singapore-based biopharmaceutical company Specialised Therapeutics (ST) has received the registration of YORVIPATH (palopegteriparatide) by the Therapeutic Goods Administration (TGA), for the treatment of chronic hypoparathyroidism in adults.

YORVIPATH was granted an Orphan Drug Designation and assessed through the TGA's Priority Review pathway. It is the first and only medicine to be listed on the Australian Register of Therapeutic Goods (ARTG) for the treatment of chronic hypoparathyroidism.

Hypoparathyroidism is a rare, complex endocrine disease, affecting an estimated 6.4-37 per 100,000 people globally. It is an endocrine disorder in which the production of parathyroid hormone (PTH) by the parathyroid glands is abnormally low or absent, causing low levels of calcium (hypocalcaemia) and high levels of phosphorous (hyperphosphataemia) in the blood.

YORVIPATH is a first-in-class PTH replacement therapy. A prodrug of parathyroid hormone (PTH [1-34]), YORVIPATH is administered subcutaneously once daily, with sustained release of active PTH designed to provide PTH levels in the physiological range for 24 hours/day.

YORVIPATH is being made available in Australia by Specialised Therapeutics (ST), under an exclusive distribution agreement with global biopharmaceutical company Ascendis Pharma A/S that covers Australia, New Zealand, Singapore, Malaysia, Brunei, Thailand, and Vietnam.

The Australian registration of YORVIPATH follows approvals issued to Ascendis Pharma by the United States Food and Drug Administration (US FDA) in August 2024 and the European Medicines Agency (EMA) in November 2023.