



NEWS RELEASE

Teijin Pharma Limited Applies for Manufacturing and Marketing Approval in Japan for New Hypoparathyroidism Treatment

Tokyo, December 13, 2024: [Teijin Pharma Limited](#) announced today that it has applied for manufacturing and marketing approval in Japan for *palopegteriparatide* (developed as TransCon PTH), a new prodrug developed by Ascendis Pharma A/S (Nasdaq: ASND) for the treatment of adults with hypoparathyroidism. The application, submitted to the Pharmaceuticals and Medical Devices Agency on December 13, 2024, is based on results of the Phase III clinical trial conducted in Japan by Ascendis Pharma. Teijin Limited, parent company of Teijin Pharma Limited, signed an exclusive licensing agreement with Ascendis Pharma on November 29, 2023.

Hypoparathyroidism is an endocrine disease caused by insufficient levels of parathyroid hormone (PTH), the primary regulator of calcium and phosphate balance in the body, which acts directly on bone and kidney and indirectly on the intestine. Individuals with hypoparathyroidism may experience a range of severe and potentially life-threatening short-term and long-term complications, including neuromuscular irritability, renal complications, extra-skeletal calcifications, and cognitive impairment.

The number of patients with hypoparathyroidism, excluding those with postoperative hypoparathyroidism, is estimated to be around 2,300 in Japan. Patients in this group who experience moderate to severe symptoms, including sensory abnormalities and significant daily life disruptions, are recognized by Japan's Ministry of Health, Labor, and Welfare as having a designated intractable disease.^{1, 2}

Current management involves the use of active vitamin D₃ preparations and oral calcium to maintain blood calcium levels. However, these treatments can cause adverse events such as hypercalcemia (excessive calcium in the blood), hypercalciuria (excessive calcium in the urine), nephrocalcinosis (buildup of calcium salts in the kidney) and urolithiasis (urinary tract stones). Therefore, there is a need for a fundamental treatment that can maintain physiological PTH levels over the long term.

Palopegteriparatide is a prodrug of PTH (1-34) for once daily subcutaneous administration. It has been developed to maintain physiologically active PTH levels for 24 hours. It is the first drug in Japan expected to fundamentally treat hypoparathyroidism. *Palopegteriparatide* has been designated as an orphan drug in Japan, the United States and the European Union. It has received regulatory approval from the European Medicines Agency (November 2023) and the U.S. Food and Drug Administration (August 2024) for the treatment of adults with hypoparathyroidism.

Teijin Pharma has been contributing to the improvement of patients' quality of life through the provision of various treatments, including pharmaceuticals such as *SOMATULINE*® and *REVCOV*® for rare diseases. Now, Teijin Pharma is committed to obtaining swift approval and rapid market introduction of *palopegteriparatide*. The company aims to help solve the challenges faced by patients, families and communities in need of greater support. The launch of new drugs for rare diseases is a key pillar of this vision.

1. Shishiba Y, Imai T, Kanmori M, et al. Prevalence of postsurgical hypoparathyroidism in Japan: Estimated from the data of multiple institutes. *J JAES JSTS*. 2017;34(1):51-56.
2. Takatani R, Kubota T, Minagawa M, et al. Prevalence of Pseudohypoparathyroidism and Nonsurgical Hypoparathyroidism in Japan in 2017: A Nationwide Survey. *J Epidemiol*. 2023;33(11):569-573.

About the Teijin Group

Teijin (TSE: 3401) is a technology-driven global group with two core businesses: high-performance materials and healthcare solutions. Established in 1918 as Japan's first rayon manufacturer, Teijin today comprises some 170 companies employing 20,000 people in 20 countries. Teijin is committed to its Purpose, "Pioneering solutions together for a healthy planet." Teijin works together with employees and external partners to achieve its Long-Term Vision, "To be a company that supports the society of the future." Teijin posted consolidated sales of JPY 1,032.8 billion (USD 6.6 billion) and total assets of JPY 1,251.0 billion (USD 8.0 billion) in the fiscal year ending March 31, 2024.

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