Lonapegsomatropin: Adis Evaluation

Key Points

- A long-acting prodrug of a human growth hormone is in development by Ascendis Pharma for the treatment of growth hormone deficiency
- Received its first pediatric approval on 25 August 2021 in the USA
- Approved for use in the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone

Summary

Lonapegsomatropin (lonapegsomatropin-tcgd; SKYTROFA®), a long-acting prodrug of somatropin (human growth hormone), is in development by Ascendis Pharma as a treatment for growth hormone deficiency in pediatric and adult patients. Lonapegsomatropin received its first approval in August 2021 in the USA for the treatment of pediatric patients at least 1 year of age (and weighing ≥ 11.5 kg) with growth failure due to inadequate secretion of endogenous growth hormone. Lonapegsomatropin is administered as a once-weekly subcutaneous injection; the sustained release of somatropin from lonapegsomatropin eliminates the need for daily somatropin injections. This article summarizes the milestones in the development of lonapegsomatropin leading to this first pediatric approval for the treatment of growth hormone deficiency.

Lamb, Y. N. Pediatr Drugs. 2021. https://doi.org/10.1007/s40272-021-00478-8