Study ID 202410_MW

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November 2024

Name of study:
A multi-country, non-interventional, observational cohort study among patients treated with recombinant human growth hormone (rhGH) treatments Genotropin® (Somatropin) and Ngenla® (Somatrogon) under routine clinical care (PROGRES 2.0)

Funding Support
Pfizer

Study period
September 2025 – August 2035

Summary
Ngenla® (somatrogon) is a once-weekly, subcutaneously administered form of rhGH, approved for the treatment of children and adolescents from 3 years of age with growth failure due to inadequate secretion of endogenous GH. There is a need for real-world data to enhance the understanding of the long-term efficacy and safety of Ngenla®. This multi-country, non-interventional, cohort study aims to gather this data via the GloBE-Reg registry from all patients of any age receiving treatment with either Ngenla® or Genotropin® as part of routine clinical practice at the discretion of the treating physician. The study will evaluate and compare the long-term effectiveness, safety, and adherence of both medications.

Inclusion criteria
– Active participants of GloBE-Reg
– Treatment with Ngenla® (somatrogon), a long-acting rhGH or Genotropin® (somatropin), a daily rhGH, at the discretion of the prescribing physician

Exclusion criteria
– Participation in any interventional clinical trial during the study period.

Data Required and Timepoints for Data Collection:
Core Data
Core Data History
GloBE-Reg rhGH Minimum Dataset

- Diagnosis Case Report Form (CRF): at the time of original diagnosis and if the diagnosis is revised
- Clinician Reported Outcome and Therapy CRFs:
  - One pre-rhGH visit (preferably 6-15 months before rhGH initiation)
  - One visit at rhGH initiation
  - All follow-up visits (any rhGH formulations or if rhGH stopped)

Timepoints for Data Cut

Data will be collected in 6 monthly tranches in July 2025, Jan 2026, July 2026, Jan 2027, July 2027…

Expected outputs

Pfizer plans to use the data for research purposes. Data will be analyzed and compared between brands to attempt to understand similarities and differences between Ngenla® and Genotropin®, ideally resulting in scientific presentations and publications. This will also involve submission of data via a study report to regulators wherever required.

Publication Plan for authorship in outputs

Pfizer intends to develop scientific publications and congress presentations in partnership with GloBE-Reg and participating PROGRES 2.0 centres. All publications will adhere to Pfizer's internal publication processes and align with ICMJE recommendations. For abstracts and manuscripts, Pfizer will invite Centre Leads from a reasonable number of representative contributing centers as co-authors. Invited authors may nominate an alternate author from among the responsible clinicians at their centre. For the final publication at the end of the study, the number of authors that will be invited for co-authorship will be limited. All centres will be properly acknowledged for their contribution and support of data generation for the study. In addition to the ICMJE recommendations, all authors for abstracts and publications will need to comply with the requirements of Pfizer's publication process and commit to the necessary deadlines and final author approval needed for submission.

Other Registration Sites

HMA-EMA Catalogue of RWD studies –EUPAS1000000705

First created: 30 Jan 2025
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