Study ID 202410_MW

Name of the Principal Investigator: Michael Wajnrajch
Contact details including institution/sponsor: Pfizer Inc. Michael.Wajnrajch@pfizer.com
Coinvestigators: Lissette M. Cespedes, Pfizer Inc.; Daria La Torre, Pfizer Inc.
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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)
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 to be collected for all participating cases: Core Data GloBE-Reg rhGH Minimum Dataset Frequency – 6 Monthly
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 (refer to guidance) Pfizer intends to drive publications in partnership with GloBE-Reg investigators. Authors will be invited to co-author publications based on the ICMJE recommendations. Authors will be invited from the Registry users contributing to the dataset.

Other Registration Sites
HMA-EMA Catalogue of RWD studies – Application to be submitted by Pfizer.