New phase 2 data for somapacitan demonstrate its potential as an efficacious once-weekly treatment for childhood growth hormone deficiency

Athens, Greece, 28 September 2018 – Somapacitan, a novel growth hormone derivative in development for once-weekly administration of growth hormone, matched the therapeutic benefits of once-daily Norditropin® (somatropin) in a phase 2 trial in children with growth hormone deficiency.¹ There are currently no approved once-weekly treatments for growth hormone deficiency. The REAL 3 trial data were presented today at the 57th Annual Meeting of the European Society for Paediatric Endocrinology in Athens, Greece.

The trial compared three somapacitan doses (0.04, 0.08 or 0.16 mg/kg/wk) to Norditropin® 0.034 mg/kg/day. Annualised height velocity did not differ significantly for the 0.08 and 0.16 mg/kg/wk doses compared to Norditropin®. The mean annualised height velocity for the three dose levels of somapacitan was 8.0 cm, 10.9 cm and 12.9 cm, respectively, as compared to 11.4 cm for daily Norditropin®. Somapacitan was well tolerated at all doses investigated, with no clinically relevant safety or local tolerability issues identified.¹

“Today children with growth hormone deficiency require daily injections, which can be a considerable treatment burden for patients and caregivers. A once-weekly treatment would represent a significant development for these children and their families, helping them to live less disrupted lives,” said lead investigator Prof Lars Sävendahl of the Karolinska Institutet and Pediatric Endocrinology Unit, Karolinska University Hospital, Stockholm, Sweden.

“The injection fatigue following years of daily administration could negatively impact adherence, thereby leading to worse treatment outcomes,” said Mads Krosggaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “In line with our long-term commitment, we are investigating the potential of somapacitan as a once-weekly growth hormone treatment for children with growth hormone deficiency.”

About the REAL 3 trial
REAL 3 was a multinational, randomised, parallel-group, active-controlled trial with the primary endpoint to evaluate the efficacy of multiple dose regimens of once-weekly somapacitan after 26 weeks of treatment in 59 growth hormone treatment-naïve pre-
pubertal children with growth hormone deficiency, compared to daily Norditropin® administration. Participants were randomised to either a dose of somapacitan (0.04, 0.08 or 0.16 mg/kg/wk) or Norditropin® 0.034 mg/kg/day. The trial demonstrated dose dependency with no statistically significant difference in height velocity between somapacitan and daily growth hormone at the two upper doses of somapacitan. The mean annualised height velocity for the three dose levels of somapacitan was 8.0 cm, 10.9 cm and 12.9 cm, respectively, as compared to 11.4 cm for daily Norditropin®. The observed safety profile in the trial was consistent with that known for Norditropin®.1,2

About somapacitan
Somapacitan is a long-acting analogue of human growth hormone which is under investigation as a possible treatment for growth hormone deficiency. Somapacitan is built on the near twenty year-long protein technology applied for prolongations of insulins, GLP-1 and now growth hormone. Somapacitan has been modified from native human growth hormone to increase its binding to the plasma protein albumin, making it suitable for once-weekly dosing.3

About childhood growth hormone deficiency
Childhood growth hormone deficiency is a rare condition in which there is not enough growth hormone circulating in the blood to ensure normal growth. Affected children experience slowed or halted growth from the age of two to three years onwards. If treatment is started early, affected children may grow to a normal height. Currently available growth hormone treatments must be administered as a daily subcutaneous injection.4-6

About Novo Nordisk
Novo Nordisk is a global healthcare company with 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 43,100 people in 79 countries and markets its products in more than 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Further information
Media:
Katrine Sperling +45 4442 6718 krsp@novonordisk.com

Investors:
Peter Hugreff Ankersen +45 3075 9085 phak@novonordisk.com
Anders Mikkelsen +45 3079 4461 armk@novonordisk.com
Valdemar Borum Svarrer +45 3079 0301 jvls@novonordisk.com
References


