Somapacitan, a once-weekly reversible albumin-binding GH derivative, in children with GH deficiency

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Video Script

This study evaluated the safety, local tolerability, pharmacodynamics and pharmacokinetics of a once-weekly drug candidate versus once-daily growth hormone in children with growth hormone deficiency. This phase 1 trial was conducted in 14 pediatric endocrinology clinics in eight countries.

The drug candidate – somapacitan – is a growth hormone derivative that binds reversibly to albumin in the blood, resulting in an extended half-life and prolonged effects. Because of this, the frequency of administration of this medication can be reduced. Somapacitan is injected subcutaneously using a prefilled pen. Clinical trials in adults have suggested the feasibility of a once-weekly dosing regimen of somapacitan based on its PK/PD profile. However, no such study has been conducted for children with growth hormone deficiency. Until now.

To evaluate its safety in children, researchers studied 32 boys and girls aged 6 to 13 with a confirmed diagnosis of growth hormone deficiency. Participants were randomly assigned to receive, over one week, either a single dose of somapacitan at one of four dose levels, or a daily dose of growth hormone.

Single doses of somapacitan within a given dose range were well tolerated when administered to pre-pubertal children with growth hormone deficiency. While a few adverse events, such as transient injection site reactions, were observed, all of these occurrences were mild. Furthermore, no anti-somatropin or anti-human growth hormone antibodies were detected.

The IGF-1 profile suggested that somapacitan is suitable for once-weekly dosing in children with growth hormone deficiency. Future clinical trials are necessary to determine whether long-term use of somapacitan results in improved outcomes in
children with growth hormone deficiency.

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