Post hoc subgroup analysis of Asian children with pediatric GHD from the global phase 3 efficacy and safety study of once-weekly Somatrogon vs. once-daily Somatropin

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Background

- A global phase 3 study compared the efficacy and safety of once-weekly somatrogon with once-daily Somatropin in pediatric subjects with Growth Hormone deficiency (GHD)

- The objective of this subgroup analysis was to evaluate the efficacy and safety of once-weekly somatrogon vs once-daily Somatropin in the subset of Asian subjects.

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Methods

- Prepubertal patients were randomized 1:1 to once weekly somatrogon (0.66mg/kg/week) or once-daily somatropin (0.24mg/kg/week) for 12months.

- The primary endpoint was height velocity (HV) at month 12; secondary endpoints included HV at month 6 and change in height standard deviation score (SDS) at months 6 and 12 and insulin-like growth factor 1 (IGF-1) SDS.

Study Population

Country	No. of participants
India	26
South Korea	12
Taiwan	2
Australia	1
Great Britain	1
New Zealand	1
Spain	1
USA	1
Total	45

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Efficacy

	Somatrogon (n=24)	Somatropin (n=21)	Treatment Difference
Primary Endpoint: HV at 12 m (cm/yr)	10.95	9.58	1.37
Secondary Endpoint: HV at 6 m (cm/yr)	11.23	8.31	2.92

Overall, mean annual HV, change in height SDS, and change in IGF-1 SDS were numerically higher in Somatrogon-treated Asian children compared with somatropin treated Asian children at all post-baseline visits.

HV-Height Velocity

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Safety and tolerability

- Most of the children experienced ≥1 AE during the study (Somatrogon, 83%; somatropin, 76%), most being **mild or moderate in severity.**
- The most common all-cause TEAEs (≥5%) reported in this Asian subgroup, irrespective of treatment group, were injection site pain, nasopharyngitis, anaemia, influenza and oropharyngeal pain.
- Once-weekly somatrogon and once-daily somatropin had comparable treatment-emergent AE (TEAE) and tolerability profiles.

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Discussion

The efficacy was consistent with findings for the full population of the phase 3 study

	LS mean estimate of HV at 12 M (Asian subset analysis – n=45)	LS mean estimate of HV at 12 M (Phase – III analysis – N= 224)
Somatrogon	10.95 cm	10.1 cm
Somatropin	9.58 cm	9.78 cm
Treatment Difference	1.37 cm	0.32 cm

In the Asian subgroup, once-weekly somatrogon had similar safety and tolerability profiles compared with once-daily somatropin, consistent with the findings from the full study population

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LS- Least Squares

- One of the key strengths of this subgroup analysis is the fact that Asian participants in this subgroup were drawn from several different countries, which extends the generalizability of the findings.

- Although the number of children was well balanced between the treatment groups, the relatively small number of children overall (within this subgroup) is a limitation of this analysis.

Conclusions

- This post hoc analysis of data from Asian children enrolled in the Somatrogon global phase 3 study confirmed that efficacy and safety data from this subgroup were consistent with those of the overall population of the phase 3 study that demonstrated that once-weekly Somatrogon is noninferior to once-daily somatropin.

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Thank you