



## Poster Presentations

P1-d3-293: Metabolic effects of LB03002, a sustained release formulation of rhGH, in children with GH Deficiency

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Background: Growth hormone has profound effects on body composition and lipid metabolism in children as well and adults. We previously demonstrated in a randomized phase III multicentre study that once weekly LB03002 is comparable to daily rhGH regarding safety and efficacy and now present data on metabolic parameters.

Objective and hypotheses: The effect of LB03002 treatment on glucose metabolism and lipid parameters was assessed.

Methods: 167 previously untreated children with growth failure (HTSDS  $\leq$  -2 unless organic GHD, HVSDS  $\leq$  -1) due to idiopathic or organic GH deficiency (GH peak  $\leq$  7 ng/mL in two tests) were randomized to receive either once weekly LB03002 (0.5 mg/kg) or once daily rhGH (0.03 mg/kg) for 12 month. Patients treated with daily rhGH were switched to weekly LB03002 in the second year.

Results: Selected growth and metabolic parameters (mean $\pm$ SD):

	First year/second year treatment	Weekly/weekly (N=87)	Daily/weekly (N=80)
HV (cm/yr)	Baseline	2.64 $\pm$ 1.11	2.87 $\pm$ 1.04
	1st year	11.72 $\pm$ 2.58	12.16 $\pm$ 3.09
	2nd year	8.33 $\pm$ 1.92	7.28 $\pm$ 2.34
Cholesterol (mmol/L)	Baseline	4.70 $\pm$ 1.60	4.51 $\pm$ 0.94
	Month 12	4.58 $\pm$ 1.49	4.43 $\pm$ 0.80
	Month 24	4.43 $\pm$ 1.33	4.22 $\pm$ 0.94
Glucose (mmol/L)	Baseline	4.01 $\pm$ 1.08	4.09 $\pm$ 0.90
	Month 12	4.40 $\pm$ 0.68	4.66 $\pm$ 0.55
	Month 24	4.56 $\pm$ 0.48	4.47 $\pm$ 0.66
HbA1c (%)	Baseline	5.07 $\pm$ 0.38	5.04 $\pm$ 0.33
	Month 12	5.13 $\pm$ 0.29	5.14 $\pm$ 0.32
	Month 24	5.35 $\pm$ 0.36	5.33 $\pm$ 0.36

Growth parameters were comparable for both groups. There were no relevant differences between treatment groups in metabolic parameters (glucose, insulin, haemoglobin A1c, cholesterol, and triglycerides). Cholesterol slightly decreased, while fasting glucose, insulin, and HbA1c increased over time but remained within the normal range. Changes from baseline of the assessed parameters were not clinically relevant. No patients developed diabetes.

Conclusions: The data show that weekly treatment with LB03002 has a comparable metabolic effect as treatment with daily rhGH.

\*In cooperation with Biopartners' and LG Life Sciences' GH Study Group

## Session Details

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