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Twenty-four months efficacy and safety of LB03002, a new sustained release formulation of rhGH, in children with GHD: Extension of a phase III randomized multicentre study*

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We previously demonstrated that once weekly LB03002, a sustained release formulation of rhGH, is comparable to daily rhGH regarding efficacy and safety after 12 months treatment in a phase III randomized multicentre study. This study was extended to assess the long-term safety and efficacy of LB03002. We now present 24 months data.

167 previously untreated children with growth failure (HTSDS ≤−2 unless organic GHD, HVSDS ≤−1) due to idiopathic or organic GH deficiency (GH peak ≤7 ng/mL in two tests) initially received either once weekly LB03002 (0.5 mg/kg) or once daily rhGH (0.03 mg/kg). After the 12 month comparative period, patients treated with daily rhGH were switched to LB03002 and all patients continued treatment with once weekly LB03002 (0.5 mg/kg) for another 12 months.

LB03002 treatment maintained growth responses with expected HV and HT gain during the second treatment year without excessive bone maturation (BA/CA). Gain in HT from baseline to month 24 and improvement in HTSDS was comparable for both groups.

Table: Efficacy data

	First year/second year treatment	Weekly/Weekly (N=87)	Daily/Weekly (N=80)
HV (cm/yr)	Baseline	2.64±1.11	2.87±1.04
	1st year	11.72±2.58	12.16±3.09
	2nd year	8.33±1.92	7.28±2.34
HVSDS	Baseline	−3.23±1.52	−3.09±1.52
	Month 12	5.74±3.35	6.26±3.66
	Month 24	2.21±1.89	1.47±1.92
Δ HTSDS	Baseline – Month 12	1.39±0.66	1.44±0.73
	Baseline – Month 24	1.95±0.92	1.92±0.95

IGF-I levels increased notably during treatment and continued to increase towards the normal range after switching from daily rhGH. No significant changes in laboratory parameters were observed and LB03002 was well tolerated.

In conclusion, expected growth rates and a good safety profile were maintained during weekly treatment with LB03002 for two years.

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